UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for Rulemaking to Revoke
the Authority for Industry to
Use Partially Hydrogenated
Vegetable Oils in Foods

Docket No. _____

submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

May 18, 2004

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CITIZEN PETITION

I. PRELIMINARY STATEMENT

The Food and Drug Administration ("FDA") concluded in November 1999 that 2,500 to 5,600 lives could be saved each year if the amount of trans fatty acids in packaged foods – but not food served in restaurants[1] – were disclosed,[2] and it concluded in July 2003 that 240 to 480 or more lives will be saved each year because of its requirement that beginning in 2006 the amount of trans fatty acids in packaged foods be disclosed.[3] It is now incumbent on the FDA to take the next step toward protecting the public health: revoking the legal authority for industry to use

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[1] Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 343(q)(5), generally prohibits the FDA from applying its 2003 trans-fat labeling requirement to food either served in a restaurant or processed and sold in a retail establishment for consumption elsewhere. However, the FDA's food labeling regulations do apply to restaurants that make a health or nutrient content claim. Section 403(r)(1)(A) of the FFDCA, 21 U.S.C. 343(r)(1)(A), says that a food is misbranded if its label contains a claim that has not been approved by the FDA, and the FDA's regulations provide that, if an approved claim is made by a restaurant, the restaurant must "provide information on the nutrient that is the basis for the claim, e.g., 'low fat, this meal contains 10 grams of fat.'" *A Guide for Restaurants and Other Retail Establishments* (FDA Center for Food Safety and Applied Nutrition February 1996) (question 73 interpreting 21 C.F.R. 101.10). The FDA has not yet approved any nutrient content or health claim for trans fat, other than establishing that products that contain less than 0.5 grams per serving can be considered to contain no trans fat. 68 Fed. Reg. at 41502.

[2] 64 Fed. Reg. 62746-62825 (November 17, 1999). (proposed rule to require that trans fatty acids be declared in the nutrition label)

[3] 68 Fed. Reg. 41434-41499 (July 11, 2003) (final rule requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements). As discussed elsewhere, the 1999 and 2003 estimates were based on different assumptions and cannot be compared.

partially hydrogenated vegetable oils[4] in both packaged foods and foods served in restaurants and other food-service establishments (where Americans now consume about 38 percent of their total fat intake[5]). Our extrapolation from the FDA's 1999 and 2003 analyses indicates that that step could save upwards of 11,000 to 30,000 additional lives each year.[6]

While some trans fatty acids[7] occur naturally in the dairy and meat products from ruminant animals, the FDA concluded in 2003 that about 80 percent of dietary trans fat comes from partially hydrogenated vegetable oils.[8] Those vegetable oils are subjected to chemical hydrogenation to increase their melting point, shelf and fry life, and flavor stability. As the FDA explained in 1999, "Through hydrogenation, oils (i.e., fats in liquid form), such as soybean, safflower, and cottonseed oil, which are rich in unsaturated fatty acids, are converted to semi-solids and solids that are useful in margarines and vegetable shortenings."[9]

This petition does not request any limitation on the trans fat that either occurs naturally in meat and dairy fats or forms during the production of nonhydrogenated oils,[10] because those

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[4] For stylistic convenience we use the term vegetable oils throughout this petition even though, in some contexts, the term includes menhaden oil, which is a fish oil, and partially hydrogenated lard.

[5] Lin B, Guthrie J, Frazao E., *Away-From-Home Foods Increasingly Important to Quality of American Diet* (United States Department of Agriculture, Economic Research Service Information Bulletin No. 749, 1999) Table 3 at 5. In 1995, 38 percent of total fat consumption occurred away from home, as compared to 18 percent in 1977-78.

[6] See *infra* sections III.C. and III.G.

[7] We agree with the FDA's 2003 definition of trans fatty acids: all unsaturated fatty acids – regardless of origin – that contain one or more isolated double bonds in a trans configuration. 68 Fed. Reg. at 41461. The FDA notes that its definition is not identical to the one used by the Institute of Medicine. In this petition we use the terms trans fat and trans fatty acids interchangeably.

[8] Calculated from data in Table 1 at 68 Fed. Reg. at 41470. CSPI is not concerned about fully hydrogenated oils, which do not contain trans fatty acids.

[9] 64 Fed. Reg. at 62749 (November 17, 1999).

[10] And so it differs from the citizen petition filed in June 2003 by Diana E. Kelly and denied, without prejudice, by the FDA in December 2003. Docket Number 2003P-0289/CPI. That petition asked the FDA to prohibit in food products trans fatty acids from any source.

amounts are small and apparently unavoidable.[11] Nor does it affect either fully hydrogenated oils, which contain negligible amounts of trans fat, or partially hydrogenated oils that may be produced by new technologies that result in negligible amounts of trans fat in the final product.

II. ACTION REQUESTED

The Center for Science in the Public Interest[12] ("CSPI") requests[13] that the FDA – consistent with its regulations[14] – immediately initiate a rulemaking to:

(1) revoke all the "generally recognized as safe" statuses[15] of partially hydrogenated oils in foods – including shortening,[16] soybean oil,[17] menhaden oil,[18] and partially

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[11] Consumers could avoid naturally occurring trans fat by eating low-fat or non-fat meat and dairy products or not eating those foods at all. Further research is needed on the health effects of the naturally occurring isomers of the trans fatty acids in beef and dairy products. The mix of isomers is different from the isomers in partially hydrogenated oil and might have different effects on health.

[12] Petitioner Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported by about 850,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

[13] This petition is submitted pursuant to section 4(e) of the Administrative Procedure Act, 5 U.S.C. 553(e), and 21 C.F.R. 10.25 and 10.30.

[14] 21 C.F.R. 170.6(c) provides that ingredients "which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."

[15] Section 201(s) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(s), excludes from the legal definition of a food additive an ingredient that "is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown...to be safe under the conditions of its intended use." An ingredient can be classified as "generally recognized as safe" by a public formal determination by the FDA, a letter from the FDA, or a self-determination by a food company.

[16] The FDA approved the use of shortening in bread, rolls, and buns when in 1977 it established a "standard of identity" for bread, rolls, and buns. 21 C.F.R. 136.110(c)(5).

[17] The FDA approved the use of vegetable oils in semi-solid foods in 1977 when it established "standards of identity" for mayonnaise, 21 C.F.R. 169.140, salad dressing, 21 C.F.R.

hydrogenated low erucic acid rapeseed oil (canola oil)[19] – so that they would be legally classified as food additives. Absent a regulation "prescribing the conditions under which such additive may be safely used," it would then be illegal to continue using those food additives;[20]

(2) revoke the current "safe conditions" for those partially hydrogenated vegetable oils that the FDA has approved as food additives;[21] and

(3) prohibit the use of any partially hydrogenated vegetable oil which is not classified as a food additive because the FDA sanctioned or approved its use prior to September 6, 1958.[22]

The FDA should also immediately announce that it will complete this rulemaking by the last year of the next Administration, *i.e.*, by 2008. This deadline seems reasonable in light of the overwhelming scientific evidence that establishes the public health risks of partially hydrogenated vegetable oil and would give the FDA time to conduct cost-benefit analyses and notice-and-comment rulemaking. Industry could be given additional time, perhaps 18 months, to switch to other ingredients.

CSPI also urges the FDA immediately (prior to deciding on the merits of the regulatory actions requested in this petition) to develop a program to encourage food manufacturers and restaurants to replace partially hydrogenated oils with the most healthful ingredients possible.

160.150, and margarine. 21 C.F.R. 166.110(a)(1) .

[18] 21 C.F.R. 184.1472(b).

[19] 21 C.F.R. 184.1555(c).

[20] Section 409(a)(2) of the FFDCA, 21 U.S.C. 348(a)(2). Absent a regulation establishing the conditions whereby a food additive can be safely used, a food that contains a food additive is adulterated and, accordingly, cannot legally be introduced into interstate commerce. See sections 402(a)(2)(C)(i), 409, and 301(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(2)(C)(i), 348, and 331(a).

[21] Such as partially hydrogenated methyl ester of rosin. 21 C.F.R. 172.515(b) and 172.615.

[22] The FDA's current regulations provide that "Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient." 21 C.F.R. 181.1(b).

As part of the requested rulemaking or if any party objects to the FDA's proposal as requested in this petition, the FDA could invite public comment on tolerances for trans fat. Considering that even conventionally processed liquid vegetable oils contain low levels of trans fat, FDA might wish to set a *de minimus* level of trans fat in conventional (refined, bleached, deodorized) oils and fully hydrogenated oils and apply the same tolerance to partially hydrogenated oils. As discussed below in section III.F., the Danish government recently limited the amount of trans fat from partially hydrogenated oils to two percent of the total fat or oil in the food.

III. BACKGROUND

A. The FDA's approval or informal acceptance of various uses of partially hydrogenated vegetable oils relied on scientific evidence from the 1980s, 1970s, and earlier that indicated that consumption of trans fat did not cause any human health problem.

Although partially hydrogenated vegetable oils had been used since the 1930s, in 1976 the Federation of American Societies for Experimental Biology ("FASEB"), at the request of the FDA, reviewed the scientific literature on the health aspects of using "hydrogenated" soybean oil as a food ingredient.[23] The FASEB was informed by the FDA in July 1976 that the FDA had given "unpublished approval" for the use of hydrogenated soybean oil as a Generally Recognized As Safe (GRAS) food ingredient because the FDA considered it to be safe and had, in particular, approved its use in food dressings and in margarine.[24] The FASEB then concluded "There is no evidence in the available information on hydrogenated soybean oil that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used as a direct or indirect food ingredient at levels that are now current or that might reasonably be expected in the future."[25]

The FDA approvals for using [partially] hydrogenated vegetable oils in food dressings and margarine were published in 1977 and are still in effect.[26]

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[23] Federation of American Societies for Experimental Biology, *Evaluation of the Health Aspects of Hydrogenated Soybean Oil As A Food Ingredient* (1976) at 4. Though the report refers to hydrogenated oil, the text clearly indicates that it was *partially* hydrogenated soybean oil that was being evaluated.

[24] *Id.* at 2.

[25] *Id.* at 30.

[26] See standards of identity at 21 C.F.R. 169.115 for French dressing, 21 C.F.R. 169.140 for mayonnaise, 21 C.F.R. 169.150 for salad dressing, and 21 C.F.R. 166.110 for margarine. None of these standards of identity explicitly refers to partially hydrogenated vegetable oil, but the nature of the products indicate that it is partially hydrogenated vegetable oil.

In August 1985 the FASEB, at the request of the FDA, reviewed the scientific literature on the health aspects of industrially produced trans fat as a food ingredient. The FASEB concluded "that the available scientific information suggests little reason for concern with the safety of dietary trans fatty acids *both* at their present and expected levels of consumption and at the present *and* expected levels of consumption of dietary linoleic acid..." (emphasis in original).[27]

The FDA relied in part on that FASEB report when it concluded in 1989 that partially hydrogenated menhaden oil – which was then used in margarine in Europe – is generally recognized as safe.[28] The FDA also said that partially hydrogenated menhaden oil "is qualitatively comparable to partially hydrogenated common edible vegetable oils, such as partially hydrogenated soybean oil, that have a long history of safe use in this country."[29]

B. In October 1993, the Center for Science in the Public Interest asked the FDA to require disclosure of the amount of trans fat and to stop misleading health claims after more refined studies done in the early 1990s that showed that consumption of trans fatty acids increased the risk of coronary heart disease, and in February 1994 CSPI petitioned the FDA to require label disclosure of the amount of trans fatty acids and to prevent misleading label claims.

In October 1993, CSPI wrote to the FDA's Commissioner, David Kessler, that ten scientific studies done in the 1990s suggested that "trans fatty acids raise blood cholesterol levels, increasing the risk of cardiovascular disease." CSPI asked the FDA both to require labels to disclose the trans fatty acid content of foods and to stop misleading labeling claims.

Four months later, in February 1994, CSPI formally petitioned the FDA to require trans fat to be labeled together with saturated fat for inclusion on nutrition labels and to limit health and nutrition claims for foods that contain significant levels of trans fatty acids.

C. In November 1999, the FDA proposed a trans-fat labeling rule for packaged foods.

In November 1999 the FDA, in response to CSPI's petition, proposed amending its labeling regulations for packaged foods (1) to require that for those foods containing at least

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[27] Federation of American Societies for Experimental Biology, *Health Aspects of Dietary Trans Fatty Acids* (August 1985) at 85.

[28] 54 Fed. Reg. 38219 (September 15, 1989) at 38220. Codified at 21 C.F.R. 184.1472(b).

[29] 54 Fed. Reg. 38220.

0.5 grams of trans fat per serving the amount of trans fat in the food be included in the amount and percent Daily Value declared for saturated fatty acids and (2) to limit health claims on foods containing significant amounts of trans fat.[30]

The FDA observed in 1999 that "Reports from the Federal Government and the NAS [National Academy of Sciences] in the late 1980's concluded that *trans* fatty acids did not appear to have deleterious health effects."[31] However, after reviewing more recent studies, the FDA concluded in 1999 "that under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL-C [low-density lipoprotein cholesterol] levels, which increases the risk of CHD [coronary heart disease]...Moreover, the similar impact on LDL-C evidenced for *trans* fatty acids, as is known for saturated fatty acids, warrants serious attention from a public health perspective."[32]

The FDA then went on to estimate the benefits of its proposed labeling rule for packaged foods. Using 1995 United States Department of Agriculture data, the FDA first estimated the sources of trans fat in the average adult diet for various products.[33] The FDA then made three alternative assumptions about how much voluntary reformulation of three products would occur as a result of the mandatory labeling on food packages.[34] Under the FDA's "maximum" scenario 100 percent of margarine would be reformulated (as compared to 30 percent of all margarine that had then been reformulated), 3 percent of bread and rolls would be reformulated, and 15 percent of cookies and crackers would be reformulated.[35] Under the "minimum" scenario, the FDA assumed only that all margarines would be reformulated.[36]

The FDA then combined these three alternative estimates of the changes in trans fat consumption with two alternative methods of estimating the subsequent decrease in coronary heart disease: One method considered the effects on only LDL-C levels; the other method examined the impact on both LDL-C and HDL-C [high-density lipoprotein cholesterol]. The FDA concluded that under the first method the reduction in the risk of coronary heart disease would range – depending on how much reformulation occurs – from 0.61 percent to 0.86 percent

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[30] 64 Fed. Reg. 62746-62825 (November 17, 1999).

[31] 64 Fed. Reg. at 62753.

[32] 64 Fed. Reg. at 62754.

[33] 64 Fed. Reg. at 62765.

[34] In addition to reformulation, the FDA assumed under all its scenarios that 45 percent of consumers would adjust their consumption slightly away from non-reformulated packaged foods based on the label information. Table 2 at 64 Fed. Reg. 62767.

[35] Column 3 of Table 2 at 64 Fed. Reg. 62767.

[36] Column 5 of Table 2 at 64 Fed. Reg. 62767.

and under the second method the reduction would range from 1.20 percent to 1.67 percent.[37] The FDA estimated that about 360,000 Americans die each year from coronary heart disease,[38] which implies that the FDA's proposed labeling rule for packaged foods would reduce the risk of coronary heart disease by between 2,196 and 3,096 annual deaths considering only the impact of LDL-C and by between 4,320 and 6,012 annual deaths considering the impact on both LDC-C and HDL-C. The FDA then took a weighted average of this range of estimates and concluded that within ten years its proposed labeling rule would prevent 7,600 cases of coronary heart disease and 2,500 deaths a year considering only the impact on LDL-C and 17,100 cases of coronary heart disease and 5,600 deaths a year considering the impact on both LDL-C and HDL-C.[39]

Those reductions can be put into context by looking at the FDA's 1999 estimate of the health impact of eliminating *all* trans fat. Using FDA's first method (considering only the impact on LDL-C), there would be an annual reduction in coronary heart disease deaths of 15,408; using the FDA's second method (considering the impact on both LDL-C and HDL-C), there would be an annual reduction of 30,096 deaths.[40] Those estimates assume that companies would replace partially hydrogenated oils in all foods with the same mixture of oils that the FDA presumed companies would use in the reformulation of margarine and baked goods. A further consideration concerns which particular saturated fatty acids would be in the replacement. Stearic acid has little or no effect on LDL-C, while lauric, myristic, and palmitic acids increase LDL-C.[41]

It is noteworthy that in 1992 Grundy estimated that the estimated 3 percent of calories contributed to the American diet by trans fat raises LDL-C by 8 milligrams per deciliter, and that that increase translates into an 8 percent increase in CHD risk, or 23,000 deaths per year (adjusted by CSPI for the approximately one-fifth of trans fat that comes from natural sources).[42]

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[37] Table 2 at 64 Feb. Reg. 62767.

[38] 64 Fed. Reg. 62772.

[39] 64 Fed. Reg. at 62772.

[40] Calculated from data for scenario 1 (column 2) in Table 2 at 64 Fed. Reg. 62767. The actual benefit would be slightly less, because the trans fat that is naturally present in vegetable oil and produced during the refining, bleaching, and deodorizing process would remain in the diet.

[41] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington, D.C. 2002. at p. 8-49. Also, while early research suggested that stearic acid might increase the risk of thrombosis, subsequent research found no evidence for that concern. Lefevre M, Kris-Etherton PM, Zhao G, et al. J Am Diet Asso. 2004;104:410-9.

[42] Grundy, S. M. (1992). "How much does diet contribute to premature coronary heart disease?" Atherosclerosis IX. Proceedings of the 9th International Symposium on

D. In 2002, the Health Council of the Netherlands recommended that trans fat should be limited to 1 percent of calories.

In a report on dietary reference intakes, the Health Council of the Netherlands recommended, among other things, that trans fat should be limited to 1 percent of calories. That amounts to about 2 grams per day for a person consuming a 2,000-calorie diet.[43]

E. In July 2002, the Institute of Medicine concluded that the consumption of trans fat is at least as unhealthful as the consumption of saturated fats and that consumption of trans fat in any amount increases the risk of heart disease.

In July 2002, the Institute of Medicine ("IOM") of the National Academies, at the request of the FDA, reviewed the scientific evidence on trans fat and concluded that "There is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD [coronary heart disease], thus suggesting a UL [Tolerable Upper Intake Level] of zero."[44] The IOM concluded that trans fat is at least as harmful to health as saturated fat[45] and recommended that "*trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet."[46]

F. In March 2003, the Danish government announced that as of January 2004 the amount of trans fat from partially hydrogenated oil would be limited to two percent of the total amount of fat or oil in the food.

In 1994, the Danish Nutrition Council ("the Council") "concluded that *trans* fatty acids in the diet promote arteriosclerosis at least as much as equivalent amounts of saturated fats and

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Atherosclerosis, Stein et al., eds., Creative Communications Ltd., Tel Aviv, Israel: 471-8.

[43] Health Council of the Netherlands. Nutrition and health–recommendations of the Health Council of the Netherlands regarding energy, proteins, fats, and carbohydrates. Ned Tijdschr Geneeskd. 2002;146:2226-9. It is unclear if the 1% figure includes naturally occurring trans fatty acids.

[44] Food and Nutrition Board of the Institute of Medicine, *Letter Report on the Dietary Reference Intakes for Trans Fatty Acids* (July 10, 2002) at 34.

[45] The IOM said "The preponderance of the data suggest that [partially] hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations." *Id.* at 13.

[46] *Id.* at 34.

probably more....An agreement was...concluded with the Danish margarine industry to reduce the *trans* fatty acid content of margarines produced in Denmark."[47]

Nine years later, in 2003, the Council concluded that "studies indicate that, gram for gram, the intake of *trans* fatty acids [from partially hydrogenated fat] as compared with saturated fatty acids is associated with an approximately 10-fold higher risk increment for the development of heart disease."[48]

The Council observed in 2003 that "a bag of popcorn, a doughnut and a large portion of French fries can...together contain about 20 grams of industrially produced *trans* fatty acids....If such food is consumed several times a week, the average daily intake of industrially produced *trans* fatty acids over months or years may be on a scale that increases the risk of heart disease considerably and may cause other health problems."[49] Accordingly, the Council recommended "that the use of industrially produced *trans* fatty acids in foodstuffs be ceased as soon as possible."[50]

In March 2003, the Danish Veterinary and Food Administration issued a final order that bans – beginning January 1, 2004 – the sale of a food if it contains trans fatty acids (other than those occurring naturally in animal fat) in excess of 2 percent of the total oil or fat in the food.[51] That ban applies to all foods, including those sold by catering establishments, restaurants, and bakeries.[52] The order also declares that the trans-fat content of a food product claiming to be free of trans fat must be less than 1 percent of the total fat or oil in the food.[53]

G. In July 2003, the FDA issued a final trans-fat labeling rule, and extrapolation from the FDA's estimate of the benefits of that rule indicates that upwards of 22,000 lives could be saved each year if trans fatty acid from partially hydrogenated vegetable oils were replaced by other fatty acids.

After reviewing the public comments on its 1999 proposed trans labeling rule and having its analysis reviewed by the Interagency Economic Peer Review, the FDA concluded in July 2003

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[47] *The Influence of Trans Fatty Acids on Health*, 4th ed. (Danish Nutrition Council 2003) at 9.

[48] *Id.* at 9.

[49] *Id.* at 42, 43.

[50] *Id.* at 10.

[51] The text of the final order is at *Id.* at 50.

[52] *Id.* at 50.

[53] *Id.* at 51.

that its final trans-fat labeling rule would save between 240 to 480 deaths a year[54] (as compared to its earlier estimate of saving 2,500 to 5,600 lives a year[55]). In 2003 the FDA estimated that Americans suffer 1.1 million heart attacks annually, with 40 percent of them fatal.[56] In 2003, the FDA said that decreasing trans fat intake by 0.5 grams per day would decrease the risk of coronary heart disease by 0.29 percent to 0.57 percent,[57] or by 1,276 to 2,508 deaths a year, and it repeatedly emphasized that those were conservative estimates.[58] The FDA also said in 2003 that current average daily consumption of trans fat from partially hydrogenated vegetable oil is 5.36 grams for men and 3.89 grams for women,[59] or an average of about 4.6 grams for both sexes.[60] Extrapolating from those findings, if the average daily consumption of trans fatty acids from partially hydrogenated oils were reduced from 4.6 grams to zero (and replaced by a mixture of saturated, monounsaturated, and polyunsaturated fatty acids), the annual number of fatal coronary heart disease cases would fall by 11,739 to 23,074,[61] depending on whether trans fat's

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[54] 68 Fed. Reg. at 41488. This final rule only requires disclosure of the amount of trans fat. In July 2003 the FDA announced that it was scrapping the rest of its 1999 proposed rule and published an advanced notice of proposed rulemaking on how to put this disclosure in context and on new nutrient-content claims. 68 Fed. Reg. 41507 (July 11, 2003).

[55] The two estimates cannot be directly compared. As discussed above in section III.C., reformulation of only margarines was just one of three scenarios assumed by the FDA in 1999. In 2003 the FDA assumed only reformulation of margarines. 68 Fed. Reg. at 41487. Judging from recent product reformulations by Frito-Lay, Nabisco, Ruby Tuesday's, and other major companies, even in 1999 the FDA underestimated the degree to which its labeling rule would influence companies to replace partially hydrogenated vegetable oil with less harmful ingredients. Voluntary company action, though, does not mitigate the need for the regulatory action that we request.

[56] 68 Fed. Reg. at 41488.

[57] 68 Fed. Reg. at 41483.

[58] See, for example, 68 Fed. Reg. at 41485 and 41488.

[59] 68 Fed. Reg. at 41469.

[60] That average consumption obscures the fact that some people who eat large amounts of foods made with partially hydrogenated oil consume much larger amounts of trans fat and have a higher than average risk of heart disease.

[61] As the FDA recognized (Table 10 at 68 Fed. Reg. at 41487), the magnitude of the health benefit from reducing the use of partially hydrogenated oil depends on what ingredients replace that oil. A probabilistic model was used by the FDA in 2003 to estimate how partially hydrogenated oil would be replaced in margarine. Our calculations assume that the same average replacement would be made in all other foods. While saturated fat might increase in some foods where solid shortenings are needed, saturated fat might decrease in other foods, such as fried

effects on only LDL-C or both LDL-C and HDL-C were considered. Thus, after taking into account the 240 to 480 deaths a year that will not occur because of trans-fat labeling, one gets an additional annual reduction of 11,499 to 22,594 deaths from coronary heart disease by eliminating from the diet trans fat from partially hydrogenated oils.

In 2003, the FDA also calculated the dollar value of the health benefits from requiring disclosure of the amount of trans fat, looking at both the dollar value of the extension of longevity and the savings in medical costs associated with reductions in nonfatal cases of coronary heart disease. Using a discount rate of 3 percent and depending on which assumptions are used, the FDA estimated the cumulative total of the benefits of its labeling rule over 20 years at $13.1 billion to $26.8 billion (compared to cumulative costs over 20 years of $139 million to $275 million),[62] depending on assumptions concerning blood lipids. As discussed above, the benefits of our proposed ban on partially hydrogenated oils appear to be about 47 times the benefits of the FDA's trans-labeling rule. Thus, a simple extrapolation indicates that the discounted cumulative dollar value (over 20 years) of the benefits of such a ban would be $616 billion to $1.260 trillion.

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foods, for which low-saturated-fat alternatives are readily available. Considering the data presented in Appendix 3, we believe our basis for estimating health benefits is reasonable.

[62] Table 12 at 68 Fed. Reg. 41490.

H. In December 2003, the Institute of Medicine concluded that it is feasible to exclude from the diet trans fat from partially hydrogenated vegetable oil.

In December 2003, the Institute of Medicine ("IOM") of the National Academies – in a report to the Department of Health and Human Services, the Department of Agriculture, and Health Canada – noted its 2002 conclusion that trans fatty acids ("TFA") are "not required in the diet" (though the IOM cautioned that eliminating all trans fat, including that from ruminant sources, might introduce undesirable effects, such as inadequate intake of protein and micronutrients).[63] The IOM went on to conclude in 2003 that "diets can be planned that provide less than 1 percent of calories from TFA provided that the only sources of TFA are naturally occurring (i.e., in meat and dairy products)."[64]

I. In April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee concluded that trans fat is "more adverse" than saturated fat with respect to coronary heart disease.

In April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee, in response to a question posed by the FDA, unanimously concluded that trans fat is "more adverse" than saturated fatty acid with respect to coronary heart disease.[65]

IV. TRANS FAT INCREASES LDL-CHOLESTEROL LEVELS AND THE RISK OF HEART DISEASE.

The central concern about trans fatty acids is that they promote heart disease by raising LDL-C levels.[66] The evidence that accumulated during the 1980s and 1990s has been evaluated by several expert committees, all of which recognized that trans fat raises LDL-C levels and the risk of heart disease.

The Report by the 2000 Dietary Guidelines for Americans Advisory Committee stated:

> These results provide convincing confirmation that LDL cholesterol is a direct cause of coronary heart disease. ... trans fatty acids are included [in a box] because a definitive body of recent experimental evidence indicates that *trans* fatty acids

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[63] *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* (Food and Nutrition Board of the Institute of Medicine, December 2003) at 5-13

[64] *Id.* at 5-14.

[65] *Food Chemical News* (May 3, 2004) at 27.

[66] 68 Fed. Reg., especially at 41442-9, 41478-89.

raise the concentration of the most dangerous form of serum cholesterol (LDL-cholesterol).[67]

The National Cholesterol Education Program stated:

LDL is the major atherogenic lipoprotein and has long been identified by NCEP as the primary target of cholesterol-lowering therapy. This focus on LDL has been strongly validated by recent clinical trials, which show the efficacy of LDL-lowering therapy for reducing risk for CHD. ... Substantial evidence from randomized clinical trials indicates that trans fatty acids raise LDL cholesterol levels, compared with unsaturated fatty acids.[68]

The American Heart Association's 2000 dietary guidelines states:

... that high total and LDL cholesterol levels are strongly related to coronary artery disease and that reductions in LDL levels are associated with reduced coronary disease risk .... The major food components that raise LDL cholesterol are saturated fatty acids, trans-unsaturated fatty acids, and, to a lesser extent, cholesterol. ... It has been established that dietary trans-unsaturated fatty acids can increase LDL cholesterol ...[69]

In 2002, the Institute of Medicine's committee on macronutrients stated:

Similar to saturated fatty acids, there is a positive linear trend between trans fatty acid intake and LDL cholesterol concentration, and therefore increased risk of

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[67] Dietary Guidelines Advisory Committee, Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, to the Secretary of Health and Human Services and the Secretary of Agriculture, U.S. Department of Agriculture, 2000 at pages 34, 37.

[68] 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," NIH Publication No. 01-3670. May 2001. At pages II-1, V-9. (http://www.nhlbi.nih.gov).

[69] Krauss, R. M., R H. Eckel, B. Howard, et al. American Heart Association Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association. Circulation. 2000;102:2284-99.

> CHD. A UL [Tolerable Upper Intake Level] is not set for trans fatty acids because any incremental increase in trans fatty acid intake increases CHD risk.[70]

Trans fat's effect on LDL cholesterol and the risk of coronary heart disease provides ample reason to take regulatory action to minimize the amount of trans fat in the food supply.[71]

V. TRANS FAT MAY BE MORE HARMFUL THAN SATURATED FAT.

In addition to promoting heart disease by raising LDL-C levels, studies suggest that trans fat promotes heart disease through other mechanisms. Preliminary evidence also suggests that trans fat may cause health problems other than heart disease.

A. Trans fat has greater adverse effects than saturated fat on blood lipids.

The FDA recognized in its final trans-fat labeling rule that trans fats not only raise LDL-C levels, but also *lower* HDL-C levels.[72] The FDA cites studies by Zock and colleagues[73] that show:

> a negative linear trend between trans fat intake and HDL-C. ... FDA finds that, for the purposes of economic analysis, it is appropriate to quantify the health benefits of trans fat labeling using regression equations describing a positive linear trend between trans fat intake and LDL-C and a negative linear trend between trans fat intake and HDL-C.[74]

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[70] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. *op. cit.* at p. 8-66.

[71] While this petition focuses on reducing trans fat, it is also important to address saturated fat, a major dietary contributor to heart disease. Saturated fat constitutes 11 to 12 percent of calories in American adult diets, several-fold more than the approximately 2.6 percent of calories coming from trans fat in the average diet of Americans three years and older. (Panel on Macronutrients, Institute of Medicine. *op. cit.* pages 8-41, 8-46) Major public education campaigns, voluntary industry action, changes in government feeding programs, and regulatory actions should be brought to bear to reduce consumption of foods containing significant amounts of saturated fat (from dairy, pork, beef, tropical oils, and other sources).

[72] 65 Fed. Reg. at 41486.

[73] Katan MB, Zock PL, Mensink RP. trans fatty acids and their effects on lipoproteins in humans. Ann Rev Nutr. 1995;15:473-93. Zock PL, Katan MB, Mensink RP. Dietary trans fatty acids and lipoprotein cholesterol. Am J Clin Nutr. 1995;61:617. Zock, PL, Mensink RP. Dietary trans-fatty acids and serum lipoproteins in humans. Current Opinions in Lipidology. 1996;7:34-7.

[74] 68 Fed. Reg. at 41486.

A 1999 "Sounding Board" article in *The New England Journal of Medicine* by five prominent researchers who have studied trans fat stated:

> Because trans fatty acids increase LDL cholesterol to levels similar to those produced by saturated fatty acids and also decrease HDL cholesterol levels, the net effect of trans fatty acids on the ratio of LDL cholesterol to HDL cholesterol is approximately double that of saturated fatty acids. ... The effect of trans fatty acids on the ratio of LDL cholesterol to HDL cholesterol was significantly larger than that of saturated fatty acids in each of the six studies that allowed a direct comparison. Collectively, these studies provide definitive evidence that trans fatty acids raise this ratio more than do saturated fatty acids.[75]

The Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2000 states: "trans fatty acids also tend to lower a protective form of serum cholesterol (HDL cholesterol)."[76]

Similarly, the American Heart Association's 2000 Dietary Guidelines states: "It has been established that dietary trans-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol."[77]

Likewise, the National Cholesterol Education Program of the National Heart, Lung and Blood Institute stated in 2001: "These studies also show that when trans fatty acids are substituted for saturated fatty acids, HDL cholesterol levels are lower, with a dose response effect observed." [78] The FDA describes the uncertainty that the National Cholesterol Education Program (NCEP) and others have expressed regarding whether HDL cholesterol is an independent risk factor for heart disease, and the agency concludes that, for the purposes of the final trans-labeling rule, focusing on LDL cholesterol was sufficient.[79] It is worth recognizing,

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[75] Ascherio AM, Katan MB, Zock PL, et al. trans fatty acids and coronary heart disease. New Engl J Med. 1999;340:1994-8. The authors also noted that trans fatty acids increase Lp(a) lipoprotein levels when they are substituted for saturated fatty acids and that they increase triglyceride levels. However, the authors noted that it is unclear whether the small increases in Lp(a) induced by trans fatty acids actually increase the risk of CHD. Likewise, the FDA considered the research on those possible additional effects of trans fatty acids to be preliminary. 68 Fed. Reg. at 41449.

[76] Dietary Guidelines Advisory Committee, *op. cit.* p.37.

[77] Krauss, R. M., R H. Eckel, B. Howard, et al., *op. cit.*

[78] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *op. cit.*

[79] 68 Fed. Reg. at 41448-9.

though, the NCEP states that "Low HDL cholesterol is a strong independent predictor of CHD."[80] It also states: "Some evidence indicates that HDL protects against the development of atherosclerosis, although a low HDL level often reflects the presence of other atherogenic factors."[81] Moreover, in the proposed and final trans-fat rules, the FDA gave substantial credence to HDL's "possible relationship" to heart disease when it made extensive cost–benefit calculations on the basis of changes in both LDL + HDL cholesterol.

Also, the Food and Nutrition Board of the Institute of Medicine told the FDA in a Letter Report in 2002 that "The preponderance of the data suggest that [partially] hydrogenated fat/trans fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations."[82]

A recent meta-analysis by Mensink et al. concluded that average partially hydrogenated shortening and stick margarine increase the ratio of total/HDL cholesterol (that is, increased that measure of CHD risk) slightly less than butter, slightly more than palm oil, and substantially more than coconut fat, tub margarine, and palm kernel oil.[83] (See Figure 1.) That is because trans fat increases LDL cholesterol almost as much as lauric, myristic, and palmitic acids, but, relative to those other fatty acids, decreases HDL cholesterol. (See Figure 2.) Also, trans fatty acids, relative to stearic acid, raise LDL cholesterol; trans and stearic have little effect on HDL cholesterol when substituted for carbohydrate.

The authors state:

> The US diet provides, on average, 2.6% of energy from *trans* [monounsaturated fatty acids][84] and nearly 13% of energy from [saturated fatty acids], so that the total replacement of trans fatty acids in the diet with carbohydrates would have a greater effect on total:HDL cholesterol than would total replacement of [saturated fatty acids]. Therefore, even low concentrations of trans [monounsaturated fatty acids] in the diet should deserve attention as a target for efforts to lower [coronary artery disease] risk.

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[80] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *op. cit.* Executive Summary, pages 3, 16, 19.

[81] *Ibid.* p. II-1.

[82] Food and Nutrition Board, Letter Report on Dietary Reference Intakes for trans Fatty Acids. *op. cit.*, at 9.

[83] Mensink RP, Zock PL, Arnold DM, et al. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. Am J Clin Nutr. 2003;77:1146-55.

[84] This average, of course, obscures the fact that some people consume far more than the average.

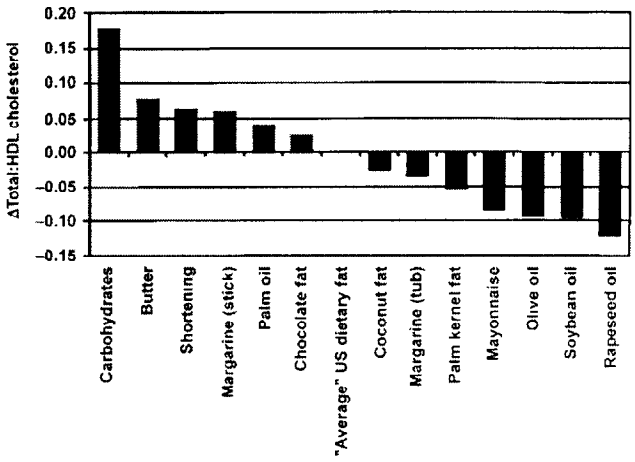

Figure 1. Predicted changes (Δ) in the ratio of serum total to HDL cholesterol when mixed fat constituting 10% of energy in the "average" U.S. diet is replaced isoenergetically with a particular fat or with carbohydrates. (From Mensink, et al., 2003)

The authors also state:

> Palm is an acceptable alternative for the industry, and, in terms of the effect on total:HDL cholesterol, palm oil is still better than the partially hydrogenated vegetable oils used [in margarine and shortening] in the food service industry. However, unhydrogenated vegetable oils produce a much more favorable lipid profile than do either palm oil or hydrogenated oils, and they should be preferred.

Mensink et al. concluded that the trans fatty acids commonly found in partially hydrogenated oils have more-adverse effects on the ratio of total/HDL cholesterol than lauric, myristic, palmitic, and stearic acids, the major saturated fatty acids in food.

In sum, a growing body of evidence, though not conclusive, indicates that trans fat, by lowering HDL-cholesterol, has greater adverse effects on serum lipids, and possibly on CHD risk, than saturated fat. Indeed, if partially hydrogenated oil were being proposed as a new food additive, the fact that it lowers HDL likely would prevent the substance from meeting the "reasonable certainty of no harm" standard for approval. However, trans fat's adverse effects on LDL cholesterol alone provides sufficient grounds to minimize the amount of industrially produced trans fat in the food supply.

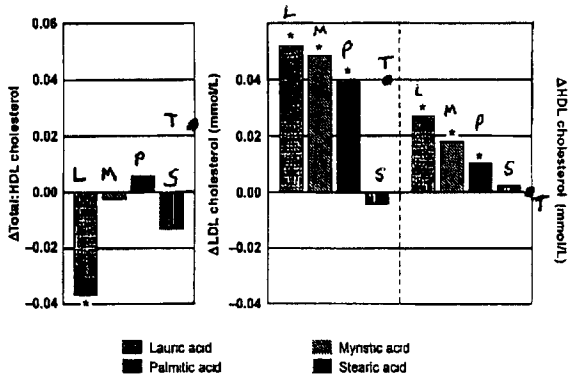

Figure 2. Predicted changes (Δ) in the ratio of serum total to HDL cholesterol and in LDL- and HDL-cholesterol concentrations when carbohydrates constituting 1% of energy are replaced isoenergetically with lauric acid ("L," 12:0), myristic acid ("M," 14:0), palmitic acid ("P," 16:0), or stearic acid ("S," 18:0). $*P < 0.001$. (From Mensink, et al., 2003) The handwritten bullet ("T") is the predicted change due to a similar replacement with trans fat (from Table 2 of the same paper).

B. Partially hydrogenated vegetable oil may be more harmful than saturated fat through mechanisms other than the effects of trans fat on blood lipids.

Beyond its adverse effects on serum lipids, trans fat may promote heart disease in additional ways. Several epidemiologic studies have found a greater association between trans fats and heart disease than would be accounted for by changes in LDL and HDL cholesterol. Though those studies cannot be considered definitive because of possible uncontrolled, confounding factors, in its final trans-fat labeling rule the FDA recognized that:

> ... the prospective studies of trans fat intake and CHD risk consistently reported a greater risk of CHD attributable to trans fat intake than would be accounted for by [changes in LDL and HDL cholesterol]. ... Thus, the results of the prospective studies suggest that there may be additional mechanisms by which trans fat contributes to CHD. ... However, FDA noted that, if there are additional mechanisms by which trans fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be greater than estimated using either Method 1 (changes in LDL-C) or Method 2 (changes in LDL-C and HDLC).[85]

[85] 68 Fed. Reg. at 41479.

The FDA also stated "that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL-C and HDL-C, by which trans fat contributes to CHD risk."[86]

Judging from a pooling of four prospective studies, a 2% increase in calories from trans fat increases the risk of heart disease by 25%. (See Table 1.) However, in the Nurses Health Study, which some researchers consider to be the best of the four studies because participants filled out dietary questionnaires four times, the increased risk of heart disease due to a 2% increase in calories from trans fat was 93%.[87] Though prospective cohort studies have methodological limitations, the pooled analysis suggests that on a gram-for-gram basis trans fat, compared to saturated fat, is a stronger promoter of heart disease.

The Institute of Medicine, too, has expressed, based on metabolic and prospective cohort studies, the concern that "dietary trans fatty acids are more deleterious with respect to CHD than saturated fatty acids."[88]

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[86] 68 Fed. Reg. at 41485.

[87] Hu FB, Stampfer MJ, Manson JE, et al. Dietary fat intake and the risk of coronary heart disease in women. N Engl J Med. 1997;337:1491-9. As noted earlier, CSPI recognizes that prospective cohort studies have methodological limitations.

[88] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. *op. cit.*, at 8-66.

Table 1. Increased Risk of Heart Disease Associated with Trans Fat, as Found in Prospective Cohort Studies[89]

Study	Relative Risk
Health Professionals Follow-up Study[90]	1.13
Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study[91]	1.14
Nurses Health Study[92]	1.62
Zutphen Elderly Study[93]	1.28
Pooled results	***1.25***

The fully adjusted relative risks of coronary heart disease for an increase of 2% of energy in trans fatty acid intake at baseline according to prospective population-based studies and the pooled variance-weighted relative risk.

The mechanisms by which trans fat may be a more powerful cause of heart disease than saturated fat are not clear.[94] But regardless of mechanism, if partially hydrogenated oil were now

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[89] Taken from Oomen CM, Ocké MC, Feskens EMJ, et al. Association between trans fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study. Lancet 2001;357:746-51.

[90] Ascherio A, Rimm EB, Giovannucci EL, et al. Dietary fat and risk of coronary heart disease in men: Cohort follow up study in the United States. BMJ 1996;313:84-90.

[91] Pietinen P, Ascherio A, Korhonen P, et al. Intake of fatty acids and risk of coronary heart disease in a cohort of Finnish men. The Alpha-tocopherol, Beta-carotene Cancer Prevention Study. Am J Epidemiol. 1997;145:876-87.

[92] Hu FB, Stampfer MJ, Manson JE, et al. *op. cit.*

[93] Oomen CM, Ocké MC, Feskens EMJ, et al. *op. cit.*

[94] Researchers have speculated that trans fatty acids promote heart disease in ways other than affecting serum cholesterol levels through small effects on lipoprotein(a) and triglycerides and also incorporation into cells involved in cardiac rhythm regulation, leading to a lower threshold for cardiac arrhythmias, a major cause of sudden cardiac death. Clevidence BA, Judd JT, Schaefer EJ, et al. Plasma lipoprotein(a) levels in men and women consuming diets enriched in saturated, cis-, or trans-monounsaturated fatty acids. Arterioscler Thromb Vasc Biol. 1997;17:1657-61. Ascherio AM, Katan MB, Zock PL, et al. *op. cit.* Lemaitre RN, King IB, Raghunathan TE, et al. Cell membrane trans-fatty acids and the risk of primary cardiac arrest. Circulation. 2002;105:697-701. Wenzel DG, Kleoppel JW. Incorporation of saturated and cis- and trans-unsaturated long chain fatty acids in rat myocytes and increased susceptibility to arrhythmias. Toxicology. 1980;18:27-36. de Roos NM, Bots ML, Katan MB. Replacement of

being proposed as a new food additive, the results of the several prospective studies likely would ring such a loud warning bell as to prevent the substance from meeting the "reasonable certainty of no harm" standard for approval. The burden would, and should, be on the applicant to prove that partially hydrogenated vegetable oil did not increase the risk of heart disease.

In addition to promoting heart disease, the hydrogenation of vegetable oil converts some of the vitamin K1 (phylloquinone) to dihydro-vitamin K1.[95] In contrast to vitamin K1, which had the expected effects on measures of bone formation and resorption, the dihydro-vitamin K1 was less absorbed and had no biological effects on bone parameters.[96] The lost vitamin K1 may pose a significant risk to people who consume inadequate levels of that nutrient. (The vitamin-K problem presumably could be solved by fortification.) Furthermore, initial studies have linked consumption of trans fats with diabetes in women (in one major study, the highest-intake quartile had a 56% greater risk than the lowest-intake quartile)[97] and possibly other health problems.[98] Thus, the health benefits from minimizing consumption of trans fatty acids from partially hydrogenated oils might be even greater than the benefits expected based on the research on heart disease.

In sum, in addition to increasing LDL-C, trans fat may increase the risk of heart disease and other health problems by decreasing HDL-C and through other mechanisms. That research, though certainly not conclusive, should be given some weight in considering the health consequences of trans fat. Indeed, in April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee unanimously concluded that trans fat is "more adverse" than saturated fatty acid with respect to coronary heart disease.[99] However, trans fat's effect on LDL-C levels alone

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dietary saturated fatty acids by trans fatty acids lowers serum HDL cholesterol and impairs endothelial function in healthy men and women. Arterioscler Thromb Vasc Biol. 2001;21:1233-7.

[95] Booth SL, Davidson KW, Lichtenstein AH, et al. Plasma concentrations of dihydro-vitamin K1 following dietary intake of a hydrogenated vitamin K1-rich vegetable oil. Lipids. 1996;31:709-13.

[96] Booth SL, Lichtenstein AH, O'Brien-Morse M, et al. Effects of a hydrogenated form of vitamin K on bone formation and resorption. Am J Clin Nutr. 2001;74:783-90.

[97] Hu FB, Manson JE, Stampfer MJ, et al. Diet, lifestyle, and the risk of type 2 diabetes mellitus in women. N Engl J Med. 2001 Sep 13;345(11):790-7. Personal communication, Frank Hu, April 8, 2004.

[98] Morris MC, Evans DA, Bienias JL, et al. Dietary fats and the risk of incident Alzheimer disease. Arch Neurol. 2003;60:194-200. Elias SL, Innis SM. Infant plasma trans, n-6, and n-3 fatty acids and conjugated linoleic acids are related to maternal plasma fatty acids, length of gestation, and birth weight and length. Am J Clin Nutr. 2001;73:807-14.

[99] *Food Chemical News. op. cit.*

provides sufficient grounds to minimize the amount of industrially produced trans fat in the food supply.

VI. NUMEROUS ALTERNATIVES TO PARTIALLY HYDROGENATED OILS EXIST OR ARE BEING DEVELOPED.

The public's, and hence the food industry's, concerns about the health effects of the trans fatty acids in partially hydrogenated vegetable oil has spurred the seed, edible oil, and food industries to develop a range of replacements for trans-containing fats. Partially hydrogenated oils can be replaced in many foods by liquid soy, corn, or canola oil. However, such substitutions with a liquid oil are not always possible due to the presence of high levels of polyunsaturated fatty acids, the need for a higher melting point, or other property. Hence, hard fats, from animal fat, tropical oils, or partially hydrogenated vegetable oils, are necessary in the production of certain foods. In recent years, seed companies, oil producers, and other companies have been developing – through breeding and chemistry – substitutes for partially hydrogenated oils (as well as for animal fats and tropical oils) that are suitable for use in most commercial food applications. Examples are shown in Appendix 1.[100]

Increased supplies of alternatives to partially hydrogenated oils will encourage more and more manufacturers and restaurant companies to reformulate some or all of their products to reduce or eliminate trans fats. In most of the cases we have identified, the reformulated product is lower in saturated-plus-trans fat than the original product, resulting in more-heart-healthful products. Examples are shown in Appendix 2.

The practicality of marketing foods without trans fat is evident in a visit to Whole Foods, a national "natural foods" supermarket chain that does not sell any foods that contain trans fats from partially hydrogenated oils.[101] The ingredient lists of various brands of crackers, cookies, and other foods, which in regular grocery stores typically contain partially hydrogenated oils, indicate that many smaller companies have been able to produce trans-free alternatives, as shown in Appendix 3. That appendix also provides examples of low-trans or trans-free foods made by mainstream food producers.

Ideally, industrially produced trans fat would be replaced largely by cis-unsaturated fat. And, as Kraft, Frito-Lay, Ruby Tuesday's, Unilever, and other companies have shown, potato chips, French fries, margarines, and other foods can be made with trans-free, liquid vegetable oils. In some products, though, such as some pastry shells, cookies, frostings, margarine, and chocolate coatings, partially hydrogenated oils can only be replaced by fats that contain sufficient

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[100] Additional methods for reducing trans fatty acids in oils and shortenings are discussed in "Questions remain over hydrogenated fats." Inform, Vol. 5 (4), April 1994, pp. 358-63. "Tools: hydrogenation, interesterification." Inform, Vol. 5 (6), June, 1994, pp. 668-78. "Stable and healthful frying oil for the 21st century." Inform, Vol. 11, June 2000, pp. 642-7.

[101] Whole Foods store visited in March 2004.

saturated fat to provide the desired performance characteristics. Some such products may contain about as much palm oil (one common solid-fat substitute) as similar products contain hydrogenated vegetable oil – and may affect the level of LDL cholesterol to similar degrees. Nevertheless, some researchers, noting the evidence that trans fat may be more conducive to heart disease than saturated fat (as discussed in section V), have stated:

> However, despite the negative effect of saturated fat on blood lipids, even replacement of industrially produced TFAs with saturated fat will, according to present knowledge, lead to a considerable reduction in [ischemic heart disease risk] and other health risks.[102]

The FDA noted in its final trans-fat labeling rule, "... the total amount of saturated fat plus trans fat in the reformulated product is commonly lower than in the original product."[103] With regard to shortenings used in baked goods, the FDA referred to comments received from industry and stated: "In these examples, the shortenings reformulated to be lower in trans fat were higher in saturated fat but were lower in total saturated fat plus trans fat than were the traditional nonreformulated shortenings."[104] Also, "FDA continues to believe that the most plausible replacement for trans fat in baked products is 50 percent cis-monounsaturated fat and 50 percent saturated fat."[105] Some food manufacturers appear to be sensitive to public concerns about saturated and trans fat and, when they are switching away from partially hydrogenated oils, are trying to reduce the total amount of those two types of fats (see Appendixes 2 and 3) [106]

In conclusion, the seed, oilseed-processing, and food industries are working hard to produce commercially viable alternatives to partially hydrogenated oils, and food manufacturers increasingly are using them. Such alternatives generally would cost no more than a fraction of a cent per serving more than partially hydrogenated shortenings.[107] In the several years that it will

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[102] Stender S, Dyerberg, J. Influence of trans fatty acids on health. Ann Nutr Metab. 2004;48:61-6.

[103] 68 Fed. Reg. at 41484.

[104] 68 Fed. Reg. at 41475.

[105] 68 Fed. Reg. at 41475.

[106] Manufacturers also should recognize that the major saturated fatty acids in foods have different effects on blood lipids, with lauric, myristic, and palmitic acids, but not stearic, increasing LDL-C and, to a lesser extent, HDL-C (Figure 2).

[107] Assuming that inter-esterified oil, high-oleic oils, and other specialty oils might cost about five to ten cents per pound more than partially hydrogenated oil, the extra cost at retail (if the cost plus margin were entirely passed along) might be 10 to 20 cents per pound (or 0.02 to 0.04 cents per gram). Cost differences in that range are within the range of price variation for partially hydrogenated oil (personal communications from industry sources). Thus, if a serving

take for the FDA to finalize regulations to implement this petition, oilseed breeders, growers (here and abroad), processors, and importers will be responding to the marketplace demand. Over that period, the costs of alternatives likely will decrease. Considering the substantial reduction in health risks and costs that would flow from reducing dietary intake of trans fatty acids, any modest increase in costs to industry (and consumers) would be a smart investment.

VII. THE FDA HAS AMPLE LEGAL AUTHORITY TO BAN THE PRESENCE IN FOODS OF TRANS FAT FROM PARTIALLY HYDROGENATED VEGETABLE OILS.

As discussed above in section III.A., for many years the FDA tacitly accepted the use of partially hydrogenated oils, and in the 1970s and 1980s the FDA formally approved various uses of partially hydrogenated vegetable oils, because the FDA believed at that time, based on prior usages in other foods and the contemporary state of scientific knowledge, that those oils were safe. However, the FDA's regulations provide that ingredients "which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."[108]

A. Partially hydrogenated vegetable oils are no longer "Generally Recognized As Safe" by the FDA and other scientists and so are food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

The regulatory scheme established by the Federal Food, Drug, and Cosmetic Act ("FFDCA") divides food ingredients into those that are "food additives" and those that are not. This distinction is important because section 409(a)(2) of the FFDCA provides that the former may be legally used only if the FDA has issued a regulation "prescribing the conditions under which such additive may be safely used."[109]

Section 201(s) of the FFDCA[110] provides, in pertinent part, a two-part test for defining when a substance is a food additive: "any substance [1] the intended use of which results or may reasonably be expected to result, directly, or indirectly, in its becoming a component or otherwise

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of food contains 10 grams of the oil, the increased cost would be 0.2 to 0.4 cents; a 5-serving package would cost about 1 to 2 cents more. Also, in some cases, companies switching from partially hydrogenated oil to canola or other oil may be able to use *less* oil, thereby actually lowering their oil costs.

[108] 21 C.F.R. 170.6(c)

[109] 21 U.S.C. 348(a)(2).

[110] 21 U.S.C. 321(s).

affecting the characteristics of any food...[2] if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use of food) to be safe under the conditions of its intended use..."

The FDA has decided that two partially hydrogenated oils are "generally recognized as safe" and, therefore, are not food additives: partially hydrogenated menhaden oil[111] and partially hydrogenated low erucic acid rapeseed oil.[112] The FDA has also determined that partially hydrogenated methyl ester of rosin is a safe food additive.[113] The FDA has also long accepted the use of other partially hydrogenated vegetable oils, presumably because – at one time – either the FDA believed such use was safe or food companies self-determined that such use was "generally recognized as safe."

There is no dispute that the intended use of any partially hydrogenated vegetable oil satisfies the first part of the legal definition of a food additive, as its intended use is to become "a component or otherwise affect the characteristics of food."

The new scientific evidence discussed both above (in sections III.E., III.H., III.I., IV., and V.) and in the FDA's final rule on trans-fat labeling demonstrates that partially hydrogenated vegetable oils now also meet the second part of the legal definition of a food additive, because they can no longer be considered Generally Recognized As Safe. Those who wish to continue using such oils – which cause thousands of deaths a year (see section III.G. above) – can no longer meet their burden [114] of showing that the oil is Generally Recognized As Safe "under the

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[111] 21 C.F.R. 184.1472(b).

[112] 21 C.F.R. 184.1555(c)(2).

[113] 21 C.F.R. 172.515(b) and 172.615.

[114] The FDA's regulations provide that the Commissioner, after reviewing the evidence, will revoke the GRAS status of an ingredient "[i]f he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act..." 21 C.F.R. 170.38(b)(3). Citing *United States v. Article of Food and Drug...Coli-Trol 80*, 518 F.2d 743,745 (5th Cir. 1975), the FDA said in 1997 that the proponent of an exemption from the definition of a food additive "has the burden of proving that the use of the substance is 'generally recognized' as safe." 62 Fed. Reg. 18937 (April 17, 1997) at 18939. However, in 1980 the FDA said – in its proposed regulation to eliminate caffeine from the list of substances that it considered to be GRAS and from the standard of identity for soda water – that "it is FDA's legal burden to take the appropriate steps to end its use as a GRAS substance." 45 Fed. Reg. 69816 (October 21, 1980) at 69819. In any event, the current scientific evidence on the public health risks of partially hydrogenated oils is so overwhelming that the FDA need not be concerned about whether it or the food industry has the

[current] conditions of its intended use." Moreover, as discussed above in section III.E., the Institute of Medicine concluded in July 2002 that any amount of trans fat intake increases the risk of heart disease,[115] and a federal Court of Appeals has held that the absence of a safe level justifies the FDA's determination that a product is unsafe.[116]

Consequently, the FDA should declare that all partially hydrogenated vegetable oils are food additives [117] (with the exceptions of those approved for use prior to September 6, 1958[118]). That includes both those partially hydrogenated oils whose uses the FDA has formally

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burden of proof.

[115] The IOM also stated that any amount of saturated fat increases the risk of heart disease. However, saturated fatty acids are integral to countless natural and traditional foods, whereas about 80 percent of trans fat is industrially produced and introduced into the diet by partially hydrogenated oil, an unnecessary ingredient. This petition does not address naturally occurring trans fat, nor does it address the low levels of trans fat that are in natural or refined, bleached, and deodorized vegetable oils. Also, it is possible that hydrogenation processes will be developed that do not introduce significant levels of trans fat. Oils produced in such ways could be considered GRAS.

[116] A federal court held that uncontradicted expert testimony that there was no known level of exposure to aflatoxin that could be considered safe supported the FDA's conclusion that corn was adulterated when it contained more than 20 parts per billion of aflatoxin. *United States v. Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th cir. 1979).

[117] Pursuant to section 409(a)(2) of the FFDCA, 21 U.S.C. 348(a)(2), the FDA could, of course, establish a "safe condition" for the use of such food additives. Section 409(a)(2) bars the use of a food additive unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used."

[118] Section 203(s) contains six specific exemptions from the definition of a food additives. We discuss below – in section VII.C. – the only one that may be relevant to this petition: "any substance used in accordance with a sanction or approval granted [by the FDA] prior to" September 6, 1958.

permitted[119] – shortening,[120] soybean oil,[121] menhaden oil,[122] and partially hydrogenated low erucic acid rapeseed oil (canola oil)[123] – and those partially hydrogenated oils whose uses the FDA has tacitly accepted.

B. The FDA should revoke the current safe conditions for those partially hydrogenated vegetable oils that it now considers to be a food additive.

Section 409(d) of the FFDCA provides that "The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons thereof."[124] The FDA's regulations provide that ingredients "which have been considered in the past by the Food and Drug Administration to be safe...must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."[125]

The new scientific evidence discussed both above (in sections III.E. III.H., III.I., IV., and V.) and in the FDA's final rule on trans-fat labeling demonstrates that it can no longer be considered safe to use any partially hydrogenated vegetable oil[126] as a food additive, unless conditions are established to ensure that the amount of trans fat is minimal.

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[119] This permission occurs either in the standards of identity for certain foods (in parts 130 *et seq.* of 21 C.F.R), in the list of substances that are generally recognized as safe by the FDA (in 21 C.F.R. part 182), in the affirmation by the FDA that a food substance is generally recognized as safe (in 21 C.F.R. part 184), or in the FDA's failure to object to a food company's self-determination that an ingredient is generally recognized as safe.

[120] The FDA approved the use of shortening in 1977 when it established a "standard of identity" for bread, rolls, and buns. 21 C.F.R. 136.110(c)(5).

[121] The FDA approved the use of vegetable oils in semi-solid foods in 1977 when it established "standards of identity" for mayonnaise, 21 C.F.R. 169.140, salad dressing, 21 C.F.R. 160.150, and margarine. 21C.F.R. 166.110(a)(1) .

[122] 21 C.F.R. 184.1472(b).

[123] 21 C.F.R. 184.1555(c).

[124] 21 U.S.C. 348(d).

[125] 21 C.F.R. 170.6(c).

[126] Such as partially hydrogenated methyl ester of rosin. 21 C.F.R. 172.515(b) and 172.615.

C. The FDA should declare that any use of partially hydrogenated vegetable oil for which the FDA issued a prior sanction or approval before September 6, 1958 is now deemed to be "unsafe" within the meaning of section 402 of the Federal Food, Drug, and Cosmetic Act.

Section 203(s)(4) of the FFDCA excludes from the definition of a food additive "any substance used in accordance with a sanction or approval granted prior to" September 6, 1958.[127] As partially hydrogenated vegetable oil has, according to the FDA, been used since the 1930s, it is possible that particular companies received such a "sanction or approval" for particular uses.[128]

Section 402(a)(2)(A) of the FFDCA provides, in pertinent part, that a food is adulterated "if it bears or contains any...added deleterious substance (other than a substance that is...a food additive...) that is unsafe...."[129] Relying on section 402 of the FFDCA, the FDA's current regulations provide that "Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient."[130]

The new scientific evidence discussed both above (in sections III.E., III.H., III.I., IV., and V.) and in the FDA's final trans-fat labeling rules demonstrates that trans fat "may be injurious to health." The FDA should, therefore, abide by its own regulations and prohibit any use of trans fat that was sanctioned or approved by the FDA prior to September 6, 1958.

VIII. THE FDA SHOULD INITIATE A PROGRAM TO ENCOURAGE FOOD MANUFACTURERS AND RESTAURANTS TO SWITCH FROM PARTIALLY HYDROGENATED OILS TO MORE HEALTHFUL OILS.

Many companies, especially small and mid-sized ones, do not understand the harmfulness of partially hydrogenated oils and may not have the expertise to identify and use safer substitutes for such oils. Also, many companies may not understand that different saturated fatty acids have different effects on the body. Hence, the FDA should develop a program to encourage food manufacturers and restaurants of all sizes to reformulate products that are now made with partially hydrogenated oils. That program should start immediately (even prior to finalizing action on the instant petition), because companies may want to reformulate their products before the 2006 deadline for labeling trans fat.

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[127] 21 U.S.C. 321(s)(4).

[128] The FDA has not listed any partially hydrogenated vegetable oil as having a prior sanction or approval. See 21 C.F.R. Part 181, Subpart B. However, a company that has such an approval or sanction is free to present it to the FDA. 21 C.F.R. 181.1(a).

[129] 21 U.S.C. 342(a)(2)(A).

[130] 21 C.F.R. 181.1(b).

The program should encourage companies to switch to the most healthful alternatives that provide the desired characteristics (recognizing the need for solid fats in some foods), minimizing the use of both partially hydrogenated oils and oils high in LDL-cholesterol-raising saturated fatty acids. Such a program to facilitate the transition to more-healthful oils should use a broad range of approaches, such as letters to all food processors, seminars in different regions of the country, information on FDA's web site, and speeches at industry conferences. Explaining how some companies have been able to switch to more healthful ingredients could be a great help to other companies.

IX. ABDICATION BY THE FDA OF ITS RESPONSIBILITY TO PROTECT THE PUBLIC HEALTH FROM THE RISKS OF PARTIALLY HYDROGENATED VEGETABLE OILS MAY LEAD STATES OR PRIVATE PARTIES TO ACT.

State and local governments are legally free to set standards that are more protective of public health than the FDA has established in those areas – such as the safety of food ingredients – for which Congress has not explicitly pre-empted such action.[131] In 1984 the Massachusetts Supreme Court upheld the ban by the Massachusetts Department of Health on the sale of any food containing ethylene dibromide ("EDB") in excess of one part per billion ("ppb"). While noting that the FDA had set a tolerance for EDB on soybeans of one ppb, the Court held that Massachusetts' statute authorized the Department's broad ban on EDB "even though Federal law allows its use." *American Grain Products Processing Institute v. Department of Public Health*, 392 Mass. 309, 315, 467 N.E.2d 455, 462 (1984). The Massachusetts Supreme Court's opinion did *not* rely on the fact that the FFDCA does not explicitly pre-empt state regulation of food additives. However, a year after the Massachusetts Supreme Court's decision, the United States Supreme Court unanimously reversed a Court of Appeals decision and held that, absent such an explicit statutory pre-emption clause, a local government can establish its own regulations governing the safety of blood plasma from paid blood donors that go beyond the FDA's standards for the collection of plasma. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985). *See also Whitehall Laboratories Division of American Home Products Corporation v. C. J. Wilbar,* 397 Pa. 223, 154 A.2d 596 (1959) (upholding Secretary of Health's decision to require – pursuant to a Pennsylvania statute – that Primatene be dispensed only by prescription even though the FDA permits it to be dispensed without prescription if its label has a warning).

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[131] By contrast Congress has provided that in certain areas a state or local government cannot have a requirement different from one established by the FDA unless the FDA grants a petition for a waiver. See, for example, standards of food, specified food labeling, medical devices, and cosmetics. Sections 403A(a)(1), 403A(a)(2)-(5), 521, and 752 of the FFDCA, 21 U.S.C. 343-1(a)(1), 343-1(a)(2)-(5), 360k, and 379s.

Private parties may in the future sue restaurants (which under the FDA's trans fat rule will not even have to disclose the amount of trans fat in their products[132]) or food companies for continuing to use partially hydrogenated vegetable oils when healthier alternatives exist. *Compare Pelman v. McDonald's*, 237 F. Supp.2d 512, 532 (S.D.N.Y. 2003) (complaint would state a tort claim "if McDonald's products are so extraordinarily unhealthy that they are outside the reasonable contemplation of the consuming public or that the products are so extraordinarily unhealthy as to be dangerous in their intended use."); *BanTransFats.Com. v. Kraft Foods North America, Inc.* CV 032041 (Marin County Superior Court of California May 2003)(alleging in paragraph 44 that trans fat meets the standard of California Civil Code section 1714.45, which provides that a manufacturer or seller is subject to product liability for a consumer product if the product is not known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community).

In sum, prompt restrictions by the FDA on the use of partially hydrogenated vegetable oils might remove the incentive for state (or local) governments or private parties to act.

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[132] That exemption applies unless the restaurant were to make an approved nutrient content or health claim about trans fat. In that event, the FDA's regulations provide that "restaurants must provide information on the nutrient that is the basis for the claim, e.g., 'low fat, this meal contains 10 grams of fat.'" *A Guide for Restaurants and Other Retail Establishment* (FDA Center for Food Safety and Applied Nutrition February 1996) (question 73 interpreting 21 C.F.R. 101.10). The FDA has not yet approved any claim for trans fat, other than establishing that products that contain less than 0.5 grams per serving can be considered to contain no trans fat. 68 Fed. Reg. at 41502.

X. CONCLUSION

For the reasons stated above, the FDA should immediately initiate (a) a rulemaking to revoke the legal authority for industry to use partially hydrogenated vegetable oils in foods[133] and (b) a program to encourage food manufacturers and restaurants to switch to safer ingredients.

XI. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

XII. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.[134]

XIII. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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Executive Director

Benjamin Cohen
Senior Staff Attorney

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[133] As mentioned in section II., as part of the requested rulemaking or if any party objects to the FDA's proposal as requested in this petition, we recognize that the FDA might invite public comment on whether it should approve partially hydrogenated oil as a food additive. CSPI would oppose that unless the amount of trans fat were limited to a *de minimus* level, similar to the Danish government's limit of two percent by weight of the total fat in a food. (Though the FDA states that under 0.5 grams of trans fat per serving of food cannot be reliably measured, it is clear that such a level would allow partially hydrogenated oils that contain 10 percent or even more trans fat. Reliable techniques are available for detecting much lower levels of trans fat.)

[134] 21 C.F.R.10.30(b).

Appendix 1. Commercially Available Substitutes for Partially Hydrogenated Vegetable (and Other) Solid and Liquid Oils
High-oleic canola, corn, soy, sunflower (NuSun), and safflower oils are relatively low in linoleic and linolenic fatty acids (which promote rancidity and reduce fry life)
Inter-esterification (ADM, others) of various oils (corn, palm, and others) with fully hydrogenated soybean oil yields products suitable for formulation of trans-free margarines and shortenings.[135]
Kraft's K-Blazer is a fat substitute made from egg white and milk protein that can be used in some baking applications.[136] Similarly, Simplesse (CP Kelco) is made from whey protein or a combination of milk and egg proteins and can be used in certain baked products.[137] Dairy-Lo, made by Parmalat, is a modified whey protein product that functions like fat in certain baked goods.[138]
Salatrim (Benefat made by Danesco), a solid at room temperature and providing fewer calories per gram than fat, consists of triglycerides made of long- (usually stearic acid) and short-chain fatty acids and can be used in some cookies, cake products, and chocolate systems.[139]
Diacylglyceride (DAG; Enova, made by ADM), made from oleic and linoleic acids, can replace some of the partially hydrogenated oil in baking shortening; it contains less than 2% trans fat by weight.[140]
Use of very long chain fatty acids (such as behenic acid, mixed with stearyl alcohol, used in Thixo, Ltd.'s oil) and emulsifiers may provide effective shortenings without trans.[141]

[135] List GR. Decreasing *trans* and saturated fatty acid content in food oils. Food Technology. 2004;58(1):23-31.

[136] Gupta MK. *Trans*-forming shortenings. Baking & Snack. Nov. 2003, 61-6.

[137] Ibid.

[138] Ibid.

[139] Ibid. Zammer CM. The trans fat dilemma. Food Processing, 2003;64(5):S30

[140] Gupta MK. Op. cit.

[141] FDA, Agency Response Letter, GRAS Notice No. GRN 000069, May 14, 2001.

Appendix 2. Products That Have Been Reformulated with Little or No Partially Hydrogenated (PH) Oil and Trans Fat[1]	
Au Bon Pain	Announced in October 2003 that it would feature trans-free muffins in which PH oil was replaced with non-hydrogenated canola oil.
Burger King	In Denmark, replaced PH oil with non-hydrogenated canola oil for frying.
Frito-Lay	Replaced PH oil with non-hydrogenated vegetable oil in numerous snack foods (including **Doritos**, **Cheetos**, **Tostitos**).
Kraft Foods	Plans to reduce or eliminate PH oil from most of its cookies and crackers by 2004 or 2005. Although the original **Oreo** still contain PH oil, in April 2004 announced three new varieties of trans-free **Oreo** cookies will be released, **New Improved Reduced Fat Oreo**, **Golden Oreo Original**, and **Golden Uh Oh! Oreo**; also in April 2004, the company announced that PH oil in seven varieties of **Triscuits** (**Original Triscuits**, **Reduced Fat, Low Sodium Triscuits**, **Deli-Style Rye Triscuits**, **Garden Herb Triscuits**, **Roasted Garlic Triscuits**, **Thin Crisps Triscuits**) was being replaced with non-hydrogenated soybean oil. In May 2004, Kraft said it would soon introduce trans-free **Ritz** and **Saltines** crackers, **Wheat Thins**, and **Nilla Wafers**.
Legal Sea Foods	Eliminated virtually all trans fat in crackers, frying oil, parfried french fries.
Masterfoods (U.K.)	In May 2003, Masterfoods UK announced the removal of PH vegetable oil from the **Mars** and **Snickers** candy bars in the UK (substitute unknown).
McCain Foods USA	In August 2003, McCain began changing from hydrogenated oil to non-hydrogenated canola oil for its **frozen potato products**.
Nestlé (U.K.)	In July 2003, Nestlé announced it would remove PH oils from its **Rolo** and **Toffee Crisp** candy bar (substitute unknown).
New York Fries (Canada)	In March 2004, this 180-outlet company replaced partially hydrogenated canola oil with non-hydrogenated sunflower oil in its **French fries**, eliminating trans and reducing saturated fat by one-third.

[1] Information from the media, companies, and supermarket surveys. Some foods marketed as trans free actually are made with partially hydrogenated oil and contain up to 0.5 grams of trans fat per serving.

Pepperidge Farm	In February 2004, the company announced a new version of Goldfish **(Goldfish Crisps)** made with non-hydrogenated sunflower and/or non-hydrogenated canola oil, instead of the PH oil used in Goldfish. All **Goldfish** cracker varieties will be trans-free by September 2004. The company eliminated PH oil from its "**Natural Whole Grain**" line of breads and plans to eliminate trans in all breads by the end of 2004.
Ruby Tuesday	In November 2003, switched from PH soybean oil to non-hydrogenated canola oil for all fried foods, including French fries. Suppliers of desserts and baked goods also will be required to eliminate PH oils.
Tyson	In February 2004 announced that over a 3-month period, it would remove PH oils from its retail breaded chicken products, such as nuggets, patties, and tenders, and its school foodservice foods, and instead use non-hydrogenated canola and other oils.
Unilever BestFoods	**Promise** margarines, are all made with liquid sunflower oil, some fully hydrogenated soy oil and PH soy oil, and trans-free **I Can't Believe It's Not Butter** spreads are "trans-free" but do contain PH soybean oil.
Voortman Cookies, Ltd.	Replaced PH soy and/or PH cottonseed oil with canola, soy, sunflower, modified palm, or palm oil (all trans-free) in several varieties of wafers and cookies.

Appendix 3. Trans-Containing and Trans-free Versions of Similar Products

Note. Serving sizes of products in a category are not always identical. Data are from labels or other company information, except where indicated. Products made with partially hydrogenated oil are in **bold**, *products containing little or no partially hydrogenated oil are in regular type All units are grams*

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source**
Cookies	**Nabisco Oreo**	**34g**	**PH*** soybean**	**7**	**1.5**	**2.5**	**4**	
	Nabisco Golden Uh-Oh Oreo	34g	palm, high-oleic canola	7	2	0	2	
	Nabisco Reduced Fat Oreo	34g	high-oleic canola, palm	4.5	1	0	1	
	Frookie Frookwich Chocolate Sandwich Cookies	31g	canola	7	2	0	2	
	Country Choice Sandwich Cremes	27g	high-oleic sunflower and/or safflower	5	0.5	0	0.5	
	365 (Whole Foods) Sandwich Cremes	27g	canola	5	0.5	0	0 5	
	Newman's Own Newman-O's cookies	28g	palm	4.5	1.5	0	1 5	
	Famous Amos Vanilla Sandwich Cookies	**33g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**NA******	**>1.5**	
	Country Choice Vanilla Sandwich Cremes	27g	oleic safflower	5	0.5	0	0.5	
	Frookie Frookwich Vanilla Sandwich Cookies	33g	soybean	6	0.5	0	0.5	
	Nabisco Nilla Wafers	**30g**	**PH soybean**	**6**	**1.5**	**2**	**3.5**	
	Keebler Golden Vanilla Wafers	**31g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**NA**	**>1.5**	
	Country Choice Vanilla Wafers	30g	oleic safflower or oleic sunflower	5	0.5	0	0.5	
	Archway Oatmeal Raisin	**29g**	**PH soybean and/or cottonseed**	**3.5**	**1**	**NA**	**>1**	
	Country Choice Oatmeal Raisin	23g	canola, high-oleic sunflower and/or high-oleic safflower	3	0.5	0	0.5	

**From product labels, telephone calls to companies, or company websites, except where indicated.

***PH=partially hydrogenated

****NA=not available

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
	Nabisco Chips Ahoy!	**33g**	**PH soybean**	**8**	**2**	**1.5**	**3.5**	
	Nabisco Reduced Fat Chips Ahoy !	32g	high oleic canola, palm	5	1 5	0	1 5	
	Newman's Own Chocolate Chip Cookies	33g	palm	7	3	0	3	
	Nabisco Fig Newtons	**31g**	**PH soybean**	**2.5**	**0**	**1**	**1**	
	365 (Whole Foods) Organic Fig Bars	38g	soybean	1	0	0	0	
	Nabisco Ginger Snaps	**28g**	**PH soybean**	**2.5**	**0.5**	**1**	**1.5**	
	American Natural & Specialty Brands Mi-Del Ginger Snaps	30g	canola	4	0	0	0	
	Nabisco Teddy Grahams Honey	**31g**	**PH soybean**	**4**	**1**	**1.5**	**2.5**	
	Hain Kidz Chocolate Animal Grahams	30g	oleic safflower	3	0	0	0	
	Our Family Farm Wild Animal Vanilla Cookies	33g	soybean	3.5	0.5	0	0.5	
	Hain Kidz Animal Crackers	28g	soybean	2	0.5	0	0.5	
Crackers	**Nabisco Wheat Thins**	**31g**	**PH soybean**	**6**	**1**	**2.5**	**3.5**	
	Giant Food Original Thin Wheats	**29g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**N/A**	**>1.5**	
	Hain Wheatettes	30g	oleic safflower	3.5	0	0	0	
	Nabisco Ritz	**16g**	**PH soybean**	**4**	**1**	**1**	**1**	NAH 9/96*
	Barbara's Rite Lite Round	15g	high-oleic safflower	1	0	0	0	
	Late July Classic Rich Crackers	15g	high-oleic safflower, palm	2	0	0	0	
	Hains Rich Baked Crackers	15g	oleic safflower	2.25#	0.5	0	0.5	
	Kraft Cheese Nips	**30g**	**PH soybean**	**6**	**1.5**	**2**	**3.5**	
	Sunshine Cheez-It	**30g**	**PH soybean and/or cottonseed**	**7.5**	**1.5**	**1.5**	**3**	CR 3 2003*
	Late July Cheddar Cheese Crackers	30g	oleic safflower	5	1.5	0	1.5	
	Nabisco Triscuits	**28g**	**PH soybean**	**5**	**1**	**1**	**2**	
	Triscuits trans-free	28g	soybean	4.5	0.5	0	0 5	Kraft Press Release
	Sunshine Soup & Oyster Crackers	**15g**	**PH soybean and/or cottonseed**	**1.5**	**0**	**NA**	**>1.5**	
	Giant Soup & Oyster Crackers	**15g**	**PH soybean and/or cottonseed**	**1.5**	**0**	**NA**	**>1.5**	
	Hain Oyster Crackers	15g	oleic safflower	1	0	0	0	

Adapted from label listing 30g serving.

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
Fish Sticks, Frozen	**Van de Kamp's Crunchy Fish Sticks**	**114g**	**PH soybean**	**13**	**2.5**	**NA**	**>2.5**	
	Mrs. Paul's Crunchy Fish Sticks	**95g**	**PH soybean**	**12**	**2.5**	**NA**	**>2.5**	
	Ian's Lightly Breaded Fish Sticks	93g	soybean	6	1	0	1	
French Fries, Frozen	**Ore-Ida Golden Crinkles**	**84g**	**PH soybean, cottonseed**	**3.5**	**1**	**0.5**	**1.5**	**CR 11/2003***
	McCain Crinkle Cut French Fries	85g	canola	4	0	0	0	
French Fries, Restaurant	**Burger King Fries, medium**	**117g**	**PH soybean**	**18**	**5**	**4.5**	**9.5**	
	McDonalds Fries, medium	**138g**	**PH soybean**	**22.5**	**5**	**5**	**10**	**CR 11/2003**
	Ruby Tuesday Fries	117g	canola	18	2	0	2	
Margarine	**Fleischmann's Original Margarine (sticks)**	**1 tbsp.**	**liquid corn oil, PH soybean**	**11**	**2**	**NA**	**>2**	
	I Can't Believe It's Not Butter 70% Vegetable Oil Spread (stick)	**1 tbsp.**	**PH and liquid soybean oils**	**10**	**1.5**	**2**	**3.5**	**CR 3/2003**
	Fleischmann's Margarine (tub)	**1 tbsp.**	**liquid corn oil, PH soybean**	**9**	**1.5**	**NA**	**>1.5**	
	Parkay 60% Vegetable Oil Spread (tub)	**1 tbsp.**	**liquid soybean, PH Soybean**	**8**	**1.5**	**NA**	**>1.5**	
	Shedd's Spread Spreadable (Sticks)	**1 tbsp.**	**PH soybean, liquid soybean**	**8**	**1.5**	**NA**	**>1.5**	
	I Can't Believe It's Not Butter 70% Vegetable Oil Spread (tub)	1 tbsp.	liquid soybean, liquid canola, hydrogenated soybean, PH soybean	10	2	0	2	
	Promise New Promise 60% Vegetable Oil Spread (tub)	1 tbsp	liquid soybean, canola, sunflower, palm oil, palm kernel oil	8	1.5	0	1.5	
Pies, Apple	**Mrs. Smith's Apple Pie**	**131g**	**PH vegetable shortening**	**17**	**3.5**	**4**	**7.5**	**NAH 2002***
	Truly Natural Apple Pie	118g	palm, soybean, canola, olive	13	5	0	5	
Pie Crusts, frozen	**Giant Foods Pie Shell Crust**	**1/8 pie**	**PH soybean and/or cottonseed**	**7**	**1.5**	**NA**	**>1.5**	
	Pillsbury Pet Ritz Pie Crust	**1/8 pie**	**PH lard**	**5**	**2**	**NA**	**>2**	
	Mother Nature's Goodies, Inc., Whole Wheat Pie Shells	25g	canola, soybean	6	1	0	1	

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
Pie Crusts, Graham Cracker, shelf-stable	**Nabisco Honey Maid Pie Crust**	**28g**	**PH oil**	**7**	**1.5**	**3**	**4.5**	
	Nabisco Nilla Pie Crust	**28g**	**PH soybean and/or cottonseed**	**7**	**1.5**	**3**	**4.5**	
	Wholly Healthy Truly Natural Graham Cracker Pie Crust	21g	palm	5	2.5	0	2.5	
Shortening	**Crisco**	**1 tbsp.**	**PH soybean and/or cottonseed**	**12**	**3**	**1.5**	**4.5**	
	Crisco All Vegetable Oil (Sticks, shelf-stable)	**12g**	**PH soybean, PH cottonseed**	**12**	**3**	**NA**	**>3**	
	Crisco All Vegetable Shortening Zero Trans	1 tbsp.	soybean oil, hydrogenated soybean oil	12	3	0	3	

CSPI Center for Science in the Public Interest
nonprofit publisher of *Nutrition Action Healthletter*

May 18, 2004

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Dear Sir or Madam:

Enclosed are: (1) the original and three copies of a petition we are submitting and (2) four copies of a letter from 28 physicians and scientists in support of our petition. Please docket both documents.

Please call me at 202-332-9110 ext. 321 if you have any questions about either of these documents.

Sincerely,

Benjamin Cohen
Senior Staff Attorney

enclosures

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