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Counsel for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

ROBERT REID, on behalf of himself and all others similarly situated,

Plaintiff,

v.

JOHNSON & JOHNSON, and MCNEIL NUTRITIONALS, LLC,

Defendants.

Case No: '11CV1310 L POR

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF:

UNFAIR COMPETITION (COMMON LAW & CALIF. BUS. & PROF. CODE §§ 17200 *ET SEQ.*);

FALSE ADVERTISING LAW (CALIF. BUS. & PROF. CODE §§ 17500 *ET SEQ.*); AND

CONSUMER LEGAL REMEDIES ACT (CALIF. CIV. CODE §§ 1750, *ET SEQ.*)

DEMAND FOR JURY TRIAL

Plaintiff Robert Reid ("Plaintiff"), on behalf of himself, all others similarly situated, and the general public, by and through undersigned counsel, hereby sues Johnson & Johnson and McNeil Nutritionals, LLC, (collectively "Defendants" or "Johnson & Johnson") and, upon information and belief and investigation of counsel, alleges as follows:

INTRODUCTION

1. Benecol® Spread and Benecol® Light Spread (collectively "Benecol") are vegetable oil spreads, like margarine. Benecol is packaged in an 8 ounce tub, which is wrapped in a 5-panel cardboard package. **Exhibits A-D**.

2. Johnson & Johnson manufactures and sells Benecol, which it markets as a functional food *Proven to Reduce Cholesterol.*

3. Johnson & Johnson markets Benecol in this manner because it contains plant stanol esters, a group of chemical compounds believed to reduce the level of low-density lipoprotein (LDL) cholesterol in blood when ingested under the correct circumstances. There are, however, "no studies demonstrating that plant stanol esters have an impact on population-based CHD morbidity and mortality rates."[1]

4. In 2000, the Food and Drug Administration approved a detailed and highly-qualified health claim for foods containing at least 1.7g of plant stanol esters per serving. *See* 21 C.F.R. § 101.83. Because Benecol contains only 0.85g plant stanol esters per serving, it does not qualify to display the FDA-approved health claim, *see* 21 C.F.R. § 101.83(c)(2)(iii)(A)(2). Benecol also lacks sufficient nutrient contribution to display the plant stanol health claim, *see id.* § 101.83(c)(2)(iii)(C). Nevertheless, for over a decade, Johnson & Johnson has packaged Benecol with an improper plant stanol health claim, rendering Bencol misbranded under the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 343(r)(1)(B).

5. Moreover, despite that Benecol does not even meet the FDA's minimum per-serving level for a claim of efficacy, Johnson & Johnson treated the FDA's approval of a health

[1] European Food Safety Authority, *Scientific Opinion: Plant stanol esters and blood cholesterol*, The EFSA Journal (2008) 825, 1-13 (Oct. 2, 2008)

claim about *plant stanol esters* as a license to make false claims and promises about *Benecol itself*, *i.e.,* that regularly consuming Benecol will reduce a person's blood cholesterol level.

6. By advertising Benecol in this manner, Johnson & Johnson rendered the product an improperly-marketed drug. *See* 21 U.S.C. § 321(g)(1)(B).

7. In addition, these claims are false because Benecol is made with partially hydrogenated vegetable oil (PHVO) containing artificial trans fat, a toxic food additive that, in the amounts present in Benecol, negatively affects blood cholesterol levels to a greater degree than any positive effect associated with plant sterol esters in the product.

8. Because the PHVO in Benecol more than counteracts any positive effect plant stanol esters may have on cholesterol levels, Johnson & Johnson's representation and promise that Benecol is *Proven to Reduce Cholesterol* is false. Johnson & Johnson also lies when it tells consumers Benecol contains *No Trans Fat*, and *No Trans Fatty Acids*, because every product made with PHVO contains trans fat.

9. Johnson & Johnson's unlawful labeling of Benecol is just one part of a long-standing, multi-faceted advertising campaign perpetrated on the American public for more than a decade, aimed at convincing consumers that using Benecol will reduce their cholesterol.

10. For example, Johnson & Johnson has promoted the product through print, web, and television advertisements, and recruits physicians to effectively "prescribe" Benecol to their patients with cholesterol issues (a practice which further renders Benecol an unapproved drug), including by providing physicians with Benecol literature and messaging to relay to their consumer-patients. *See, e.g.*, **Exhibit E** (Benecol Physician Brochure). By enlisting physicians in this manner, Johnson & Johnson bolsters the appearance that Benecol's claim of reducing cholesterol is credible and substantiated by medical science, which it is not.

11. Plaintiff Robert Reid repeatedly purchased Benecol during the class period in reliance on Johnson & Johnson's false representations and promises that Benecol contains an amount of plant stanol esters that may reduce the risk of heart disease when used as directed, that Benecol is *Proven to Reduce Cholesterol*, and that Benecol contains *No Trans Fat*.

12. Having become aware of the true nature of Benecol and Johnson & Johnson's

misleading tactics complained of herein, Plaintiff seeks, on behalf of himself and all others similarly situated, the remedies prayed for herein, *i.e.*, for an order compelling Defendants to (a) cease marketing Benecol using the misleading tactics complained of herein, (b) conduct a corrective advertising campaign, (c) restore the amounts by which Defendants were unjustly enriched, and (d) destroy all misleading and deceptive materials and products.

THE PARTIES

12. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey.

13. Defendant McNeil Nutritionals, LLC, is a Delaware corporation with its principal place of business in Pennsylvania, and is a wholly-owned operating subsidiary of Johnson & Johnson. McNeil is subject to Johnson & Johnson's control and the companies share employees, resources and accounts. Defendants manufacture, market and sell Benecol.

14. Plaintiff Robert Reid is a resident of San Diego, California.

JURISDICTION AND VENUE

15. This Court has original jurisdiction under 28 U.S.C. §1332(d)(2) (The Class Action Fairness Act) because the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs and more than two-thirds of the members of the Class reside in states other than the state of which Defendants are citizens.

16. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Plaintiff resides in and suffered injuries as a result of Defendants' acts in this district, many of the acts and transactions giving rise to this action occurred in this district, and Defendants (1) are authorized to conduct business in this district and have intentionally availed themselves of the laws and markets of this district through the promotion, marketing, distribution, and sale of its products in this district; (2) reside in this district; and (3) are subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

The Role of Cholesterol in Heart Disease

17. Cholesterol is a sterol, a subgroup of steroids, which are a class of organic

molecule that occurs naturally in plants, animal and fungi.

18. Cholesterol is a waxy, fat-like substance found in the body's cell walls. The body uses cholesterol to make hormones, bile acids, vitamin D, and other substances. The body makes all the cholesterol it needs, which circulates in the bloodstream in packages called lipoproteins. There are two main kinds of lipoproteins, low density lipoprotein, or LDL, and high density lipoprotein, or HDL.

19. LDL cholesterol is sometimes called "bad" cholesterol because it carries cholesterol *to* tissues, including the arteries. Most cholesterol in blood is LDL cholesterol. The higher the level of LDL cholesterol, the greater the risk for heart disease.

20. HDL cholesterol is sometimes called "good" cholesterol because it takes cholesterol *away* from tissues to the liver, where it is removed from the body. A *low* level of HDL cholesterol increases the risk for heart disease.

21. If there is too much cholesterol in the blood, some of the excess can become trapped in artery walls. Over time, this builds up and is called plaque. The plaque can narrow vessels and make them less flexible, a condition called atherosclerosis.

22. This process can happen to the coronary arteries in the heart, which may restrict the provision of oxygen and nutrients to the heart, causing chest pain or angina. Moreover, some cholesterol-rich plaques can burst, causing a blood clot to form over the plaque, blocking blood flow through the artery—and causing a heart attack.

23. When atherosclerosis affects the coronary arteries, the condition is called coronary heart disease, and is sometimes referred to simply as "heart disease."

24. The following represents total cholesterol, LDL cholesterol, and HDL cholesterol guidelines (measured as milligrams per deciliter of blood) promulgated by the U.S. Department of Health & Human Services, the National Institutes of Health, and the National Heart, Lung and Blood Institute:

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Total Cholesterol	
Less than 200 mg/dL	Desirable
200-239 mg/dL	Borderline High
240 mg/dL and above	High
LDL Cholesterol	
Less than 100 mg/dL	Optimal (Ideal)
100-129 mg/dL	Near Optimal
130-159 mg/dL	Borderline High
160-189 mg/dL	High
190 mg/dL and above	Very High
HDL Cholesterol	
Less than 40 mg/dL	Major Heart Disease Risk Factor
50 mg/dL and above	Gives Some Protection Against Heart Disease

25. The consumption of saturated fat negatively affects blood cholesterol levels because the body reacts to saturated fat by producing cholesterol. This has a greater effect on cholesterol levels than the direct consumption of dietary cholesterol.

26. But it is the consumption of *artificial trans fat* that has the most pernicious and dramatic effect on blood cholesterol of any known nutrient, because the consumption of trans fat *both* increases "bad" LDL cholesterol and decreases "good" HDL cholesterol.

The Strong Evidence of Artificial Trans Fat's Health Hazards

27. Trans fat is naturally found in trace amounts in foods derived from ruminant animals, primarily in cow's milk and red meat.[2] It is also found in small quantities in human breast milk. Also known as vaccenic acid, natural trans fat has never been linked to any negative health effect in human beings and is chemically different from artificial trans fat. Initial studies

[2] Dariush Mozaffarian *et al., Trans Fatty Acids and Cardiovascular Disease*, 354 New Eng. J. Med. 1601, 1608 (2008).

on rats indicate that consumption of vaccenic acid is beneficial to health.[3]

28. Artificial trans fat, by contrast, is manufactured via an industrial process called partial hydrogenation, in which hydrogen atoms are added to normal vegetable oil by heating the oil to temperatures above 400 degrees Fahrenheit in the presence of ion donor catalyst metals such as rhodium, ruthenium, and nickel.[4] The resulting product is known as partially hydrogenated vegetable oil, or PHVO, which is a major ingredient in Benecol Spread.

29. Spreads like Benecol are the main source of artificial trans fat in the American diet.[5]

30. PHVO was invented in 1901 and patented in 1902 by German chemist Wilhelm Normann. PHVO molecules chemically differ from the natural fat molecules in other food products. The industrial process that adds hydrogen ions to normal vegetable oil improves food texture and permits food products to withstand heavy mechanical processing and high temperatures.[6]

31. PHVO was initially a "wonder product" attractive to the packaged food industry because it combines the low cost of unsaturated *cis* fat with the flexibility and long shelf life of saturated fat. Like *cis* fat, PHVO is manufactured from lower-cost legumes,[7] while saturated fat is derived from relatively expensive animal and tropical plant sources.[8] Given its versatility,

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[3] Ye Wang *et al., Trans-11 Vaccenic Acid Dietary Supplementation Induces Hypolipidemic Effects on JCR:LA-cp Rats*, 138 J. Nutrition 2117 (November 2008).

[4] *See* Alice H. Lichtenstein, *Trans Fatty Acids, Plasma Lipid Levels, and Risk of Developing Cardiovascular Disease*, 95 Circulation 2588, 2588-90 (1997).

[5] *See* Mozaffarian, 354 New Eng. J. Med. at 1608.

[6] *See* Alberto Ascherio *et al.*, *Trans Fatty Acids & Coronary Heart Disease*, 340 New Eng. J. Med. 94, 94-8 (1999). *See also* Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Questions & Answers About Trans Fat Nutrition Labeling (Update 2006) (2003), *available at* http://www.cfsan.fda.gov/%7Edms/qatrans2.html

[7] e.g., corn oil, soybean oil, peanut oil

[8] e.g., butter, cream, tallow, coconut oil

PHVO was recently used in 40 percent of processed packaged foods.[9]

32. Artificial trans fat does not exist in nature, and the human body has not evolved to digest it. The same unusual and unnatural chemical structure that gives artificial trans fat properties attractive from an industrial perspective makes it highly toxic to human health.

33. In particular, PHVO causes cardiovascular heart disease, diabetes and cancer.

- **Cardiovascular Disease**

34. In a joint Dietary Guidelines Advisory Committee Report, the U.S. Department of Health and Human Services and the U.S. Department of Agriculture recognized **"[t]he relationship between trans fatty acid intake and LDL cholesterol is direct and progressive, increasing the risk of cardiovascular disease."**[10]

35. Food products with artificial trans fat harm the heart by "rais[ing] the concentration of the most dangerous form of serum cholesterol (LDL cholesterol)" and "lower[ing] a protective form of serum cholesterol (HDL cholesterol)."[11]

36. The American Heart Association notes that, **"trans fats raise your bad (LDL) cholesterol levels and lower your good (HDL) cholesterol levels. Eating trans fats increases your risk of developing heart disease."**[12]

37. After an extensive evaluation of the scientific literature on the connection between the consumption of artificial trans fat and coronary heart disease, the FDA concluded:

> [B]ased on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trials and prospective cohort studies) that were conducted using a range of test conditions and across different geographical

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[9] Mary Carmichael, *The Skinny on Bad Fat*, Newsweek, Dec. 1, 2003, at 66. *See also* Kim Severson, *Hidden Killer. It's **Trans** Fat. It's Dangerous. And It's In Food You Eat Every Day*, S.F. Chron., Jan. 30, 2002.

[10] Dep't of Health & Human Serv. & U.S. Dep't of Agric., 2005 Dietary Guidelines Advisory Committee Report, Section 10 (2005).

[11] *Id.*

[12] Am. Heart Ass'n., *Trans Fat Overview*, *available at* http://www.americanheart.org/presenter.jhtml?identifier=3045792.

> regions and populations . . . the available evidence for an adverse relationship between trans fat intake and CHD risk is strong.[13]

38. Trans fat raises the risk of CHD more than any other known nutritive product.[14]

39. Removing 2% of daily calories from trans fat from the American diet "would prevent approximately 30,000 premature coronary deaths per year, and epidemiologic evidence suggests this number is closer to 100,0000 premature deaths annually."[15]

40. A study on the impact of trans fatty acids on heart health provides evidence that:

> [E]ven the lower estimates from the effects [of PHVO] on blood lipids would suggest that more than 30,000 deaths per year may be due to the consumption of partially hydrogenated vegetable fat. Furthermore, the number of attributable cases of nonfatal coronary heart disease will be even larger.[16]

41. Since "the adverse effect of trans fatty acids is stronger than that of saturated fatty acids," saturated fat consumption would need to be reduced by 10 percent of caloric intake to have the same impact.[17]

42. "10 to 19 percent of CHD events in the United States could be averted by reducing the intake of trans fat."[18]

43. By raising LDL levels and lowering HDL levels, trans fat causes a wide variety of dangerous heart conditions, including low flow-mediated vasodilation, coronary artery disease, and primary cardiac arrest.

44. After conducting a crossover diet trial, Danish researchers determined that healthy

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[13] Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Questions & Answers About Trans Fat Nutrition Labeling.

[14] Mozaffarian, 354 New Eng. J. Med. at 1603.

[15] Alberto Ascherio *et al.*, *Trans Fatty Acids & Coronary Heart Disease*, 340 New Eng. J. Med. 94, 94-8 (1999).

[16] W.C. Willett *et al., Trans Fatty Acids: Are the Effects only Marginal?* 84 Am. J. Pub. Health 722, 723 (1994).

[17] Mozaffarian, 354 New Eng. J. Med. at 1609.

[18] *See* Mozaffarian, 354 New Eng. J. Med. at 1611.

men and women who maintained a high-trans fat diet had 21 percent lower protective HDL levels and 29 percent lower flow-mediated vasodilation ("FMD") than those on a high-saturated fat diet. FMD measures the percent increase between the diameter of the artery at ordinary and at maximum dilation, and low FMD is "a risk marker of coronary heart disease.[19]

45. Australian researchers observed that heart attack patients possess elevated amounts of trans fat in their adipose tissue, strongly linking heart disease with long-term consumption of trans fat.[20]

46. By taking blood samples from 179 survivors of cardiac arrest and 285 randomly-selected control patients and comparing the top fifth with the bottom fifth of participants by trans fat intake, another study published in the American Heart Association's *Circulation* found that the largest consumers of trans fat have three times the risk of suffering primary cardiac arrest, even after controlling for a variety of medical and lifestyle risk factors.[21]

- **Type 2 Diabetes**

47. Artificial trans fat causes type 2 diabetes.[22]

48. In particular, trans fat disrupts the body's glucose and insulin regulation system by incorporating itself into cell membranes, causing the insulin receptors on cell walls to malfunction, and I turn elevating blood glucose levels and stimulating further release of insulin.

49. Researchers at Northwestern University's medical school found mice show multiple markers of type 2 diabetes after eating a trans fat diet for only four weeks. By the eighth week of the study, mice fed the diet high in trans fat showed a 500% increase compared to the control group in hepatic interleukin-1β gene expression, one such marker of diabetes, indicating

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[19] Nicole M. De Roos *et al.*, *Replacement of Dietary Saturated Fatty Acids by Trans Fatty Acids Lowers Serum HDL Cholesterol and Impairs Endothelial Function in Healthy Men and Women*, 21 Am. Heart Assoc. 1233, 1233-37 (2001).

[20] Peter M. Clifton *et al.*, *Trans Fatty Acids In Adipose Tissue And The Food Supply Are Associated With Myocardial Infarction*. 134 J. of Nutrition 874, 874-79 (2004).

[21] Rozenn N. Lemaitre *et al.*, *Cell Membrane Trans-Fatty Acids and the Risk of Primary Cardiac Arrest*, 105 Circulation 697, 697-701 (2002).

[22] Am. Heart Ass'n., *Trans Fat Overview*.

the extreme stress artificial trans fat places on the body.[23]

50. A 14-year study of 84,204 women found that for every 2 percent increase in energy intake from artificial trans fat, the relative risk of type 2 diabetes was 1.39. In other words, each 2 percent of calories from artificial trans fat increases the risk of type 2 diabetes by 39 percent.[24]

- **Breast, Prostate, and Colorectal Cancer**

51. Trans fat is a carcinogen and causes breast, prostate, and colorectal cancer.

52. A 13-year study of 19,934 French women showed 75 percent more women contracted breast cancer in the highest quintile of trans fat consumption than did those in the lowest.[25]

53. In a 25-year study of 14,916 U.S. physicians, the doctors in the highest quintile of trans fat intake had over a 100% greater risk of developing prostate cancer than the doctors in the lowest quintile.[26]

54. A study of 1,012 American males observing trans fat intake and the risk of prostate cancer found "[c]ompared with the lowest quartile of total trans-fatty acid consumption, the higher quartiles gave odds ratios (ORs) equal to 1.58," meaning those in the highest quartile are 58% more likely to contract prostate cancer than those in the lowest.[27]

55. A 600-person study found an 86 percent greater risk of colorectal cancer in the

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[23] Sean W. P. Koppe *et al.*, *Trans fat feeding results in higher serum alanine aminotransferase and increased insulin resistance compared with a standard murine high-fat diet*, 297 Am. J. Physiol. Gastrointest Liver Physiol. G378-84 (2009).

[24] Jorge Salmeron *et al.*, *Dietary Fat Intake and Risk of Type 2 Diabetes in Women*, 73 Am. J. of Clinical Nutrition 1019, 1023 (2001).

[25] Véronique Chajès *et al.*, *Association between Serum Trans-Monounsaturated Fatty Acids and Breast Cancer Risk in the E3N-EPIC Study.* 167 Am. J. of Epidemiology 1312, 1316 (2008).

[26] Jorge Chavarro *et al.*, *A Prospective Study of Blood Trans Fatty Acid Levels and Risk of Prostate Cancer.*, 47 Proc. Am. Assoc. of Cancer Research 95, 99 (2006).

[27] Xin Liu *et al.*, *Trans-Fatty Acid Intake and Increased Risk of Advanced Prostate Cancer: Modification by RNASEL R462Q Variant*, 28 Carcinogenesis 1232, 1232 (2007).

highest trans fat consumption quartile.[28]

56. A 2,910-person study found "trans-monounsaturated fatty acids . . . were dose-dependently associated with colorectal cancer risk," which showed "the importance of type of fat in the etiology and prevention of colorectal cancer."[29]

57. There is no health benefit to artificial trans fat consumption and "no safe level" of artificial trans fat intake.[30]

58. According to the established consensus of the scientific community, consumers should keep their consumption of trans fat "as low as possible."[31]

59. As Dr. Dariush Mozaffarian notes in the New England Journal of Medicine:

> [T]rans fats from partially hydrogenated oils have no intrinsic health value above their caloric value. Thus from a nutritional standpoint, the consumption trans fatty acids results in considerable potential harm but no apparent benefit. . . . Thus, complete or near-complete avoidance of industrially produced trans fat—a consumption of less than 0.5 percent of the total energy intake—may be necessary to avoid adverse effects and would be prudent to minimize health risks.[32]

60. The serious health conditions caused by trans fat consumption only occur from consuming artificial trans fat, not the trace natural trans (vaccenic acid) fat found in ruminant sources:

61. Of four prospective studies evaluating the relation between the intake of trans fatty acids from ruminants and the risk of CHD, none identified a significant positive association, whereas three identified nonsignificant trends toward an inverse association. . . . [T]he sum of the current evidence suggests that the public health implications of consuming trans fats from

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[28] L.C. Vinikoor *et al.*, *Consumption of Trans-Fatty Acid and its Association with Colorectal Adenomas*, 168 Am. J. of Epidemiology 289, 294 (2008).

[29] Evropi Theodoratou *et al.*, *Dietary Fatty Acids and Colorectal Cancer: A Case-Control Study*, 166 Am. J. of Epidemiology 181 (2007).

[30] Food & Nutrition Bd., Inst. of Med., Dietary Reference Intakes For Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (2005).

[31] Food & Nutrition Bd., Inst. of Med., Dietary Reference Intakes For Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids 424 (2005).

[32] Mozaffarian, 354 New Eng. J. Med. at 1608-1609.

ruminant products are relatively limited.[33]

62. In 2008, California became the first state to ban all restaurant food with artificial trans fat, a law affecting approximately 88,000 eating establishments. Trans fats now may not be served in California's schools or restaurants, Cal. Educ. Code § 49431.7, Cal. Health & Saf. Code § 114377.

63. New York City banned all trans fat in its 20,000 food establishments in 2006. Similar laws exist in Philadelphia; Baltimore; Stamford, Connecticut; and Montgomery County, Maryland.

64. A 2004 Danish law restricted all foods to under 2 percent of calories from trans fat. Switzerland made the same restriction in 2008.[34] Thus Benecol Spread, prominently touted as a heart healthy product on its package, is illegal in these nations because it raises LDL cholesterol levels, inflames blood vessels, and causes heart disease.

65. After conducting a surveillance study of Denmark's trans fat ban, researchers concluded the change "did not appreciably affect the quality, cost or availability of food" and did not have "any noticeable effect for the consumers."[35]

66. In 2006, a trans fat task force co-chaired by Health Canada and the Heart and Stroke Foundation of Canada recommended capping trans fat content at 2 percent of calories for tub margarines and spreads and 5 percent for all other foods. On September 30, 2009, British Columbia became the first province to impose these rules on all restaurants, schools, hospitals, and special events.[36]

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[33] Mozaffarian, 354 New Eng. J. Med. at 1608-1609.

[34] Andrew Collier, *Deadly Fats: Why Are We still Eating Them?*, The Independent (UK), June 10, 2008.

[35] Mozaffarian, 354 New Eng. J. Med. at 1610; *see also* High Levels of Industrially Produced Trans Fat in Popular Fast Food, 354 New Eng. J. Med. 1650, 1652 (2006).

[36] *Province Restricts Trans Fat in B.C.*, British Columbia Ministry of Healthy Living and Sport Press Release (2009), *available at* http://www2.news.gov.bc.ca/news_releases_2005-2009/2009HLS0013-000315.htm.

Plant Stanol Esters

67. Sterols are a subgroup of steroids, a class of organic molecule that occurs naturally in plants, animals and fungi. The most familiar type of animal sterol is cholesterol, which plays a vital role in cellular function, forming part of the cell membrane.

68. Phytosterols are sterols found in plants that have a cellular function similar to cholesterol in animals. More than 40 phytosterols have been identified. They are found widely throughout the plant kingdom and are present in many edible fruits, vegetables, nuts, seeds, cereals and legumes.

69. Stanols are saturated sterols, lacking a double bond in the sterol ring structure. They are found in the lipid fractions of cereal grains like wheat, rye and corn, and in vegetable oils.

70. In Western populations, the daily intake of plant sterols ranges from 150 to 400 milligrams per day, while the daily intake of plant stanols ranges from about 15 to 50 milligrams per day.

71. Sterols and stanols found in nature are said to be "free." Using sterols or stanols in food, however, generally requires a procedure called esterification, by which the free sterols or stanols are rendered fat-soluble.

72. The amount of stanol in a food product can be measured either as esterified, or expressed as the equivalent weight of free (*i.e.*, un-esterified) stanols. Plant stanol esters contain about 59% free plant stanols.

73. Benecol claims its cholesterol-reducing function from the presence of plant stanol esters. Benecol is primarily comprised of an esterified blend of two specific stanols, sitostanol and campestanol.

74. The consumption of plant stanols has been shown to lower LDL cholesterol under certain circumstances by inhibiting the absorption of dietary and endogenously-produced cholesterol from the small intestine. Because high LDL cholesterol levels are associated with high risk of heart disease, studies showing the effect of plant stanols in reducing LDL cholesterol suggest a beneficial effect on the risk and incidence of CHD. *See* 21 C.F.R. § 101.83(a).

75. The required daily dietary intake level of plant stanol esters that has been associated with a potential reduced risk of coronary heart disease is 3.4 grams per day, 21 C.F.R. § 101.83(c)(2)(i)(G)(2), which should be consumed in two servings eaten at different times of the day, *id.* § 101.83(c)(2)(i)(H). As a result, the FDA permits foods containing a minimum of 1.7 grams of plant stanol ester per serving to include the following health claim in the food's labeling:

> Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ___ grams of plant stanol esters.

See 21 C.F.R. § 101.83(c)(2) (specific requirements for claim); *id.* § 101.83(c)(2)(iii)(A)(2) (minimum plant stanol ester requirement); *id.* § 101.83(e) (model claims).

Benecol Contains Insufficient Plant Stanol Esters to Make a Plant Stanol Health Claim

76. Benecol is a vegetable oil spread in the same category as butter and margarine.

77. The reference amount customarily consumed (RACC) for "Butter, margarine, oil, shortening" is 1 Tablespoon. 21 C.F.R. § 101.12(b), Table 2. Thus, the RACC for Benecol is 1 Tablespoon, which is also Benecol's standard serving size, equal to 14 grams.

78. Benecol contains 0.85g of plant stanol esters per serving. Thus, Benecol does not meet the minimum requirement of 1.7g of plant stanol esters per serving necessary to make the FDA-approved plant stanol health claim. *See* 21 C.F.R. § 101.83(c)(2)(iii)(A)(2).

79. As a result, Benecol is misbranded pursuant to 21 U.S.C. §§ 343(a) & 343(r).

Benecol Fails the Minimum Nutrient Contribution Requirement for a Plant Stanol Claim

80. To make a plant stanol esters health claim as prescribed in 21 C.F.R. § 101.83, a spread like Benecol must meet the minimum nutrient contribution requirement set forth in 21 C.F.R. § 101.14(e)(6). *See* 21 C.F.R. § 101.83(c)(2)(iii)(D).

81. Section 101.14(e)(6) provides that a food meets minimum contribution requirements when it contains "10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed *prior to any nutrient addition*." 21 C.F.R. § 101.14(e)(6) (emphasis

added).

82. Although Benecol contains 10% of the Daily Reference Value for vitamin A, Johnson & Johnson achieves that mark by *adding* vitamin A to Benecol, in the form of Vitamin A Palmitate, one of the ingredients in Benecol. Thus, Benecol does not provide "10 percent or more of the . . . Daily Reference Value for vitamin A . . . *prior to any nutrient addition*," and thus fails to meet 21 C.F.R. § 101.83(C)(2)(iii)(D)'s minimum nutrient contribution requirement.

83. As a result, Benecol is misbranded pursuant to 21 U.S.C. §§ 343(a) & 343(r).

Benecol's Prohibited Use of a Plant Stanol Claim is Also False

84. As discussed above, because Benecol contains an insufficient amount of plant stanol esters, and does not meet the minimum nutrient contribution requirement, Johnson & Johnson was prohibited from using a § 101.83 plant stanol health claim in Benecol's labeling. Nevertheless, throughout the class period, Benecol always contained the following statement:

> PRODUCTS CONTAINING 0.7 G OR MORE OF PLANT STANOL ESTERS PER SERVING EATEN TWICE A DAY WITH MEALS FOR A DAILY INTAKE OF AT LEAST 1.4 G MAY REDUCE THE RISK OF HEART DISEASE AS PART OF A DIET LOW IN SATURATED FAT AND CHOLESTEROL. A SERVING OF BENECOL® [LIGHT] SPREAD CONTAINS 0.85 G OF PLANT STANOL ESTERS.

85. This statement is false, as federal law provides the correct amount of plant stanol esters necessary to achieve a possible reduction in the risk of heart disease is *3.4g* per day, not *1.4g*, as Johnson & Johnson misrepresents.

86. Moreover, federal law provides that products containing at least *1.7g* or more of plant stanol esters per serving, eaten twice a day with meals, may reduce the risk of heart disease, not *0.7g*, as Johnson & Johnson misrepresents.

87. In sum, Benecol's label is both (a) misbranded because it uses a modified version of a plant stanol esters health claim that may not be used on Benecol at all, and (b) false and misleading because the information conveyed does not accurately reflect the scientific knowledge, understanding and consensus of the daily intake amount of plant stanol esters necessary to achieve a possible reduction in the risk of heart disease.

88. Benecol's packaging includes the following directions for use, near the Nutrition

Facts panel:

> **DIRECTIONS:** Use at least 2 servings of spread per day with your meals and snacks. Each serving contains 0.85g of Plant Stanol Esters (0.5g plant stanols). BENECOL® Spreads can help you meet the National Cholesterol Education Program Guidelines recommended amount of 2 g plant stanols/sterols per day.

89. By following the directions provided and using 2 servings of Benecol per day, a consumer would not ingest the amount of plant stanol esters that has been determined to be potentially effective in reducing the risk of heart disease. Moreover, by contrasting plant stanol *esters* and plant stanols without sufficient explanation, and by citing the National Cholesterol Education Program Guidelines' recommendation of 2g of plant stanols per day, Johnson & Johnson contradicts the information provided in the improper front-label plant stanol health claim, and further confuses consumers as to the amount of plant stanol esters necessary to achieve a possible reduction in the risk of heart disease.

Benecol's *Proven to Reduce Cholesterol* Claim is False & Misleading

90. Throughout the class period, Johnson & Johnson has always claimed on its labeling that Benecol is *Proven to Reduce Cholesterol*.

91. For example, both the Benecol tub and the 5-panel packaging surrounding the tub claim Benecol is *Proven to Reduce Cholesterol*. Exs. A-D.

92. Johnson & Johnson bolsters this message through a series of related claims in Benecol's labeling.

93. For example, the inside of the 5-panel packaging states:

> **About Benecol**
>
> The name BENECOL® brings together Bene, meaning "good" and col, for "cholesterol". BENECOL® offers you a great way to reduce your cholesterol with a delightfully good-tasting spread. Did you know that 2 or more servings of BENECOL® Spreads each day:
>
> ✓ **Reduces** "bad" (LDL) cholesterol
>
> ✓ **Reduces** total cholesterol
>
> ✓ **Works** to further reduce cholesterol for those on cholesterol-lowering statin medications
>
> ✓ **Blocks** cholesterol from being absorbed into your body

94. Johnson & Johnson's representation, claim and promise that Benecol will reduce cholesterol is false. While there are studies supporting the conclusion that plant stanol esters, taken under the correct circumstances, may reduce the risk of heart disease through the intermediary step of reducing LDL cholesterol, there are no studies supporting Johnson & Johnson's claim that Benecol itself, as formulated (as opposed to the plant stanol esters in Benecol), is effective in reducing blood cholesterol.

95. Benecol contains more PHVO than plant stanol esters.

96. The trans fat in the PHVO in Benecol has a more substantial negative effect on blood cholesterol levels than any positive effect of the plant stanol esters in Benecol.

97. Even if the plant stanol esters in Benecol had a more positive effect on blood cholesterol levels than the negative effect of trans fat, though, Johnson & Johnson's claim would nevertheless be highly misleading, since the trans fat would negate much of the claimed impact of Benecol on cholesterol.

98. In addition, even if Benecol reduced cholesterol, the claim would still be highly misleading because, at the level of Benecol consumption needed to achieve that effect, the trans fat a person would consume would expose him or her to increased risk of many other diseases.

99. Therefore, Johnson & Johnson's claim that Benecol is *Proven to Reduce Cholesterol*, and similar representations, claims and promises that Benecol will reduce a consumer's cholesterol levels, are false and misleading.

The *Proven to Reduce Cholesterol* Claim Renders Benecol an Improperly-Marketed Drug

100. Under 21 U.S.C. § 321(g)(1), products that are intended to affect the structure or function of the body, or for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, are drugs.

101. The regulatory classification of a product under the FDCA is determined by its intended use, as evidenced by, among other things, its labeling and advertising, the circumstances of its marketing, sale and use, and the manufacturer's knowledge that a product is being used for a purpose for which it is neither labeled nor advertised. *See* 21 C.F.R. § 201.128.

102. Johnson & Johnson's claim that Benecol is *Proven to Reduce Cholesterol*, and

related claims (such as *Reduces "bad" (LDL) cholesterol* and *Reduces total cholesterol*) is a therapeutic claim that renders Benecol a drug within the meaning of 21 U.S.C. § 321(g)(1)(B), because the statements suggest Benecol may be useful in treating the condition of hypercholesterolemia, *i.e.*, high cholesterol.

103. That Benecol is a drug is further evidenced by Johnson & Johnson's heavily marketing Benecol through the use of physician intermediaries, who are acted to effectively "prescribe" Benecol to patients with hypercholesterolemia.

104. In approving a plant stanol ester health claim in 2000, the FDA found that ingesting plant stanol esters is generally recognized as safe. The FDA did not, however, conduct a review of Benecol itself, or make the determination that Benecol is generally recognized as safe and effective.

105. Because Benecol is not generally recognized as safe and effective when used as labeled, it is a new drug as defined in 21 U.S.C. § 321(p). New drugs may not be legally marketed in the United States without prior approval from the FDA as described in 21 U.S.C. §355(a).

106. Benecol is also misbranded under 21 U.S.C. § 352(f)(1) because its labeling fails to bear adequate directions for use for the condition for which it is offered, i.e., hypercholesterolemia.

107. Moreover, because Johnson & Johnson's claim that Benecol is *Proven to Reduce Cholesterol* lacks substantiation, it is misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and 343(r)(6).

No Trans Fat and _No Trans Fatty Acids_ are Unauthorized Nutrient Content Claims

108. Throughout the class period, Benecol's packaging contained the representations that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*.

109. FDA regulations permit the use of defined nutrient content claims.

110. *No Trans Fat* and *No Trans Fatty Acids* have not been defined by the FDA.

111. Therefore, each claim is an unauthorized nutrient content claim, rendering Benecol misbranded pursuant to 21 U.S.C. §§ 343(a) & 343(r).

Claims that Benecol Contains *No Trans Fat* or *No Trans Fatty Acids* are False

112. Benecol contains artificial trans fatty acids. Therefore, these statements are false.

Mr. Reid's Benecol Purchases

113. Plaintiff Robert Reid repeatedly purchased Benecol in California during the class period defined herein. Mr. Reid initially purchased Benecol at Albertsons, located at 3925 Mission Avenue, Oceanside, CA 92054, about four years ago, and continued to purchase Benecol there for about a year. Plaintiff later began purchasing Benecol at Stater Brothers, located at 3770 Mission Avenue, Oceanside, CA 92054, and purchased Benecol there for approximately two years. Plaintiff then began purchasing Benecol at the Marine Commissary, located at Marine Corp. Base Camp Pendleton, Building 20850, Camp Pendleton, CA 92055. Plaintiff last purchased Benecol approximately five months ago.

114. Plaintiff purchased Benecol after being exposed to, understanding, and relying upon Defendants' advertisements, representations, claims and promises, direct or indirect, that (a) because of its plant stanol esters, Benecol may be effective in reducing the risk for coronary heart disease when used as directed, (b) that Benecol is *Proven to Reduce Cholesterol*, and (c) that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*. These representations, and Benecol's overall packaging, including images of hearts and vegetables, conveyed a clear overall message that Benecol is "good for you." Plaintiff purchased Benecol, despite its expensive price, because of these specific and general representations and messages.

Johnson & Johnson's Benecol Advertising Campaign

115. In addition to the representations, claims and promises discussed above, made in Benecol's labeling, Benecol's labeling and packaging contains a number of heart graphics and depictions, conveying the false and misleading message that Benecol is a heart-healthy product. Benecol's label also depicts vegetables, which misleadingly suggests the product's healthfulness and reinforces Johnson & Johnson's deceptive messaging. Similarly, the product's name, "Benecol," misleadingly suggests the product benefits cholesterol, as Johnson & Johnson explains in the inside of the 5-panel packaging.

116. Benecol's packaging also includes a section titled "Diet Tip," in which Johnson &

Johnson tells consumers that Benecol "contain[s] an extremely low level of trans fat," and that "The FDA allows foods containing less than 0.5 grams of trans fat/serving to be labeled 0 grams trans fat, since this is considered an insignificant amount."

117. This statement is false and misleading in light of the overwhelming scientific evidence showing there is no "safe level" of artificial trans fat consumption. Moreover, the FDA has not, as Johnson & Johnson represents, determined that amounts of trans fat below 0.5g per serving are "insignificant" from a health perspective, but has repeatedly held the opposite, that trans fat consumption should be "as low as possible."

118. In addition to the labels and packaging depicted in Exhibits A-D hereto, Johnson & Johnson has advertised and marketed Benecol through a number of channels, always repeating the common messages, that (a) because of its plant stanol esters, Benecol may be effective in reducing the risk for coronary heart disease when used as directed, (b) that Benecol is *Proven to Reduce Cholesterol*, and (c) that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*.

119. Benecol's labeling references the Benecol Website, www.benecolUSA.com.

120. Doing so renders the Benecol Website labeling subject to FDA regulation.

121. The Benecol Website provides a variety of information relating to the product, frequently repeating the same false and misleading representations and promises detailed herein, and bolstering the common messages described above.

122. The Benecol Website, and any prior version, is expressly incorporated into this Complaint.

123. Johnson & Johnson also created a *physician* website, ostensibly dedicated to providing physicians with more "technical" information about Benecol's purported benefits. The Benecol Physician Website (alternatively titled "BenecolProfessionalUSA") is located at www.benecolphysicians.com.

124. The Benecol Physician Website, and any prior version, is expressly incorporated into this Complaint.

125. Benecol was also promoted in a similar fashion in print advertisements, for example, in free-standing inserts, and in coupons, some of which Plaintiff was periodically

exposed to, saw, read and relied on.

126. Benecol was also promoted in a similar fashion in television commercials including, for example, a television commercial with the following transcript:

> *Looking for a simple way to help lower your cholesterol? Try Benecol Spread, a heart-healthy alternative to butter. Benecol contains an ingredient that helps block cholesterol absorption and has a delicious, buttery taste. Make Benecol part of your healthy lifestyle.*[37]

Plaintiff's Reliance and Injury

127. When purchasing Benecol, Plaintiff was seeking a product that would lower and not negatively affect his LDL and total cholesterol levels. Moreover, Plaintiff sought a product that was generally healthy and which did not contain any toxic ingredients that would negatively affect his LDL, HDL and total blood cholesterol levels and expose him to a greater risk of diabetes, cancer, and heart disease.

128. Like other members of the classes, Plaintiff saw, understood, and relied on the Benecol labels attached hereto as Exhibits A-D, and on related Benecol advertising, when he made his decision to purchase Benecol.

129. Plaintiff purchased Benecol believing it had the qualities he sought based on Johnson & Johnson's false and misleading statements, but the products were actually unsatisfactory to him for the reasons described herein.

130. Moreover, like all reasonable consumers and members of the classes, Plaintiff considers a label's compliance with federal law a material factor in his purchasing decisions. Plaintiff is generally aware that the federal government carefully regulates packaged food labels and therefore has come to trust that information conveyed on packaged food labels is truthful, accurate, complete, and fully in accordance and compliance with federal law. As a result, Plaintiff trusts he can compare competing products on the basis of their labeling claims, to make purchasing decision affecting his health.

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[37] *Available at* http://benecolusa.com/generic.jhtml?id=benecol/include/commercial.inc.

131. Like all reasonable consumers and members of the classes, Plaintiff would not purchase a food product he knew was misbranded under federal law, *see* 21 U.S.C. § 343, which the federal government prohibits selling, *id.* § 331, and which carries with its sale criminal penalties, *id.* § 333. Plaintiff could not trust that the label of a product misbranded under federal law is truthful, accurate and complete.

132. Similarly, like all reasonable consumers and members of the classes, Plaintiff would not purchase a food product he knew was an illegally marketed new drug for which the FDA has not determined its safety and efficacy.

133. In light of the foregoing, reasonable consumers, including Mr. Reid and other members of the classes, were and are likely to be deceived by Johnson & Johnson's advertising and marketing practices as detailed herein.

134. Benecol cost more than similar products without misleading labeling, and would have cost less absent the false and misleading statements. Plaintiff purchased Benecol instead of competing products based on the false statements and misrepresentations described herein.

135. Plaintiff paid more for Benecol, and would have been willing to pay less, or nothing at all, if he had not been misled by the representations and practices complained of herein. Plaintiff would not have purchased Benecol at the prices he did, or at all, absent reliance on these material representations. For these reasons, Benecol was worth less than what Plaintiff paid for it, and likely worth nothing at all.

136. Instead of receiving a product that has the cholesterol-reducing advantages of plant stanol esters as Johnson & Johnson claims, Plaintiff received a product made with artificial trans fat, which negatively affects blood cholesterol levels to a greater extent than any positive effect from the plant stanol esters, and in any event negates much of the purported benefit of such plant stanol esters, and exposes Plaintiff to further disease and malady.

137. Plaintiff lost money as a result of Defendants' deception in that Plaintiff did not receive what he paid for.

138. Plaintiff altered his position to his detriment and suffered damages in an amount equal to the amount he paid for Benecol Spread.

DELAYED DISCOVERY

139. Plaintiff did not discover that Johnson & Johnson's labeling of Benecol was false, deceptive, or misleading until early April 2011, in talking to someone knowledgeable about the subject. While Plaintiff knew that consumption of artificial trans fat was generally worse than other types of dietary fat intake, he was unaware that, at the amounts present in Benecol, the trans fat actually counteracts any positive effect from the plant stanol esters in the product. Moreover Plaintiff was unaware of the grave health consequences of consuming products made with PHVO, like Benecol, before that time, or of the connection between the consumption of artificial trans fat and disease. Plaintiff was also unaware that the consumption of artificial trans fat affects blood cholesterol levels far more than dietary cholesterol or saturated fat.

140. Plaintiff is not a nutritionist, food expert, or food scientist; he is a lay consumer who did not possess the specialized knowledge of Johnson & Johnson, which otherwise would have enabled him to associate partially hydrogenated oil with artificial trans fat, and artificial trans fat with disease. Like nearly all consumers, Plaintiff does not read scholarly publications such as The Journal of Nutrition,[38] The European Journal of Clinical Nutrition,[39] and The New England Journal of Medicine.[40] Further, even today knowledge of the extensive use of artificial trans fats, including that they necessarily exist where partially hydrogenated oil is used as an ingredient in a food product, is generally unknown to the average consumer.

141. Moreover, many of the unlawful labeling practices complained of herein were of the nature of omissions and violations of federal law, and like members of the classes and nearly all consumers, Plaintiff is not an expert on FDA regulations.

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[38] Peter M. Clifton *et al.*, *Trans Fatty Acids In Adipose Tissue And The Food Supply Are Associated With Myocardial Infarction*. 134 J. of Nutrition 874, 874-79 (2004).

[39] A. Tavani *et al. Margarine intake and risk of nonfatal acute myocardial infarction in Italian women*. Eur. J. Clin. Nutr. 51: 30–32 (1997) (estimating a 50% greater risk of heart attack in women with high consumption of margarine, an association "independent of body mass index, history of hypertension and hyperlipidemia.")

[40] "10 to 19 percent of CHD events in the United States could be averted by reducing the intake of trans fat." 354 New Eng. J. Med. at 1611.

142. Thus, Plaintiff, in the exercise of reasonable diligence, could not have discovered Johnson & Johnson's deceptive practices earlier.

CLASS ACTION ALLEGATIONS

143. Plaintiff brings this action on behalf of himself and the following Classes in accordance with Rule 23 of the Federal Rules of Civil Procedure:

Restitution Class - All persons (excluding Defendants' officers, directors, and employees) who purchased Benecol® Spread or Benecol® Light Spread on or after January 1, 2000, in the United States, for their own or household use, rather than resale or distribution.

Injunctive Relieve Class – All persons (excluding Defendants' officers, directors and employees) who commonly purchase or are in the market for Benecol® Spread or Benecol® Light Spread in the United States for their own or household use, rather than resale or distribution.

144. Questions of law and fact common to Plaintiff and the Class include:

(a) Whether Defendants contributed to, committed, and/or is responsible for the conduct alleged herein;

(b) Whether Defendants' conduct constitutes the violations of laws alleged herein;

(c) Whether Defendants acted willfully, recklessly, negligently, or with gross negligence in the violations of law alleged herein;

(d) Whether class members are entitled to injunctive relief; and

(e) Whether class members are entitled to restitution.

145. By purchasing and/or using Benecol, all members of the classes were subjected to the same wrongful conduct.

146. Absent Defendants' material deceptions, misstatements, and omissions, Plaintiff and other members of the classes would not have purchased Benecol.

147. Plaintiff's claims are typical of the class' claims. Plaintiff will fairly and adequately protect the interests of the classes, has no interests that are incompatible with the interests of the classes, and has retained counsel competent and experienced in class litigation.

148. The classes are sufficiently numerous, as they include at least tens of thousands of individuals who purchased Benecol throughout the United States during the class period.

149. Class representation is superior to other options for the resolution of the controversy. The relief sought for each class member is small. Absent the availability of class action procedures, it would be infeasible for class members to redress the wrongs done to them.

150. Defendants have acted on grounds applicable to the classes, thereby making appropriate final injunctive relief or declaratory relief concerning the classes as a whole.

151. Questions of law and fact common to the classes predominate over any questions affecting only individual members

152. Class treatment is appropriate under FRCP 23(a) and both 23(b)(2) and 23(b)(3). Plaintiff does not contemplate class notice if the class is certified under FRCP 23(b)(2), which does not require notice, and notice via publication if the class is certified under FRCP 23(b)(3) or if the Court determines class notice is required notwithstanding that notice is not required under FRCP 23(b)(2). Plaintiff will, if notice is required, confer with Defendants and seek to present the Court with a stipulation and proposed order on the details of a class notice plan.

FIRST CAUSE OF ACTION

Violations of the California Unfair Competition Law,

Bus. & Prof. Code §§ 17200 *et seq.*

(Unlawful)

153. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth in full herein.

154. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

155. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the False Advertising Law and the Consumer Legal Remedies Act.

156. Defendants' conduct is further "unlawful" because it violates the Federal Food, Drug, and Cosmetic Act ("FFDCA") in at least following respects:

a. Benecol violates 21 U.S.C. § 343(a), which deems food misbranded when the label contains a statement that is "false or misleading in any particular";

b. Benecol contains an unauthorized plant stanol esters health claim, in violation of 21 C.F.R. § 101.83, rendering Benecol misbranded pursuant to 21 U.S.C. § 343(r);

c. Benecol contains two unauthorized nutrient content claims, *No Trans Fat*, and *No Trans Fatty Acids*, rendering Benecol misbranded pursuant to 21 U.S.C. § 343(r);

d. Benecol is an unapproved new drug pursuant to 21 U.S.C. § 321(g)(1)(B), which may not be legally marketed in the U.S. pursuant to 21 U.S.C. § 355(a);

e. Benecol's labeling violates 21 C.F.R. § 1.21, which prohibits true statements about ingredients in food that are misleading in light of the presence of other ingredients.

157. Defendants' conduct likewise violates The California Sherman Food, Drug, and Cosmetic Law ("Sherman Law"), which incorporates all the regulations and requirements of the Federal Food, Drug and Cosmetic Act. Specifically, Defendants acted in contravention of the following Sherman Law Provisions:

- § 110100 (adopting all FDA regulations as state regulations);
- § 110290 ("In determining whether the labeling or advertisement of a food . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food . . . or consequences of customary use of the food . . . shall also be considered.");
- § 110390 ("It is unlawful for any person to disseminate any false advertisement of any food . . . . An advertisement is false if it is false or misleading in any particular.");
- § 110395 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food . . . that is falsely advertised.");
- § 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.");
- § 110400 ("It is unlawful for any person to receive in commerce any food . . . that is falsely advertised or to deliver or proffer for delivery any such food . . . .");
- § 110660 ("Any food is misbranded if its labeling is false or misleading in any particular.");
- § 110670 ("Any food is misbranded if its labeling does not conform with the requirements for nutrient content or health claims as set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act and the regulations adopted pursuant thereto.");
- § 110680 ("Any food is misbranded if its labeling or packaging does not conform to

the requirements of Chapter 4 (commencing with Section 110290).");

- § 110705 ("Any food is misbranded if any word, statement, or other information required pursuant to this part to appear on the label or labeling is not prominently placed upon the label or labeling and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.");
- § 110760 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.");
- § 110765 ("It is unlawful for any person to misbrand any food."); and
- § 110770 ("It is unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.").

158. All of the challenged statements made by Defendants, by violating the FFDCA and the Sherman Law, further violate the "unlawful" prong of the UCL.

159. By violating the California Unfair Competition Law, Defendants also violated the common law of unfair competition.

160. Defendants leveraged their deception to induce Plaintiff and members of the classes to purchase products that were of lesser value and quality than advertised.

161. Plaintiff suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: he was denied the benefit of the bargain in purchasing Benecol. Had Plaintiff been aware of Defendants' false and misleading advertising tactics, he would have been willing to pay less than what he did for Benecol, or not purchase it at all.

162. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective advertising campaign.

163. Plaintiff also seeks an order for the restitution of all monies from the sale of Benecol Spread, which were unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

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SECOND CAUSE OF ACTION

Violations of the California Unfair Competition Law

Bus. & Prof. Code §§ 17200 *et seq.*

(Unfair and Fraudulent)

164. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth in full herein.

165. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

166. The false and misleading labeling of Benecol, as alleged herein, constitutes "unfair" business acts and practices because such conduct is immoral, unscrupulous, and offends public policy. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

167. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "fraudulent" business acts and practices because Defendants' conduct is false and misleading to Plaintiff, Class members, and the general public.

168. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective advertising campaign.

169. Plaintiff also seeks an order for the restitution of all monies from the sale of Benecol, which were unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

THIRD CAUSE OF ACTION

Violations of the California False Advertising Law,

Bus. & Prof. Code §§ 17500 *et seq.*

170. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth in full herein.

171. In violation of Bus. & Prof. Code § 17500 *et seq.*, the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and

use of the products without the knowledge that Benecol contained toxic artificial trans fat.

172. Defendants either knew or reasonably should have known that the labels on Benecol were false and also misleading.

173. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, and restitution.

FOURTH CAUSE OF ACTION

Violations of the Consumer Legal Remedies Act,

Civ. Code §§ 1750 *et seq.*

174. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth in full herein.

175. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

176. Defendants' policies, acts, and practices were designed to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

b. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

c. § 1770(a)(9): advertising goods with intent not to sell them as advertised.

d. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

177. As a result, Plaintiff and the classes have suffered irreparable harm and are entitled to actual damages, punitive damages, injunctive relief and restitution.

178. The conduct descried herein by Defendants was long-standing, continuing even after Plaintiff demanded the conduct cease in a CLRA letter, was done for profit as a deliberate corporate policy rather than an isolated incident, and was morally wrong, fraudulent, callous, and oppressive.

179. In compliance with Civ. Code § 1782, Plaintiff sent written notice to Defendants of his claims more than 30 days before seeking damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself, all others similarly situated, and the general public, pray for judgment and relief against Defendants as follows:

A. Declaring this action to be a proper class action.

B. An Order enjoining Defendants from misbranding Benecol in violation of the Federal Food, Drug and Cosmetic Act;

C. An order enjoining Defendants, so long as Benecol is made with PHVO, from marketing Benecol in any manner deemed to be false or misleading, including, for example:

a. Marketing Benecol with the misleading product name, "Benecol";

b. Marketing Benecol as "Proven to Reduce Cholesterol," or any equivalent, such as "offers you a great way to reduce your cholesterol," "reduces 'bad' (LDL) cholesterol," "reduces total cholesterol," "works to further reduce cholesterol for those on cholesterol-lowering statin medications," "blocks cholesterol from being absorbed into your body," and "proven ability to lower cholesterol";

c. Advertising Benecol as containing "No Trans Fat," or "No Trans Fatty Acids";

d. Marketing Benecol using images or graphics of hearts;

e. Marketing Benecol using the word "healthy"; and

f. Marketing Benecol through the use of intermediary physicians.

D. An order compelling Defendants to conduct a corrective advertising campaign to inform the public that:

a. Benecol contains less plant stanol esters than the amount which has been shown may be effective in reducing the risk of heart disease;

b. Benecol contains artificial trans fat, which counteracts any positive effect of the plant stanol esters in Benecol on any purported reduction of total cholesterol

E. An order requiring Defendants to disgorge or return all monies, revenues, and profits obtained by means of any wrongful act or practice.

F. An order compelling Defendants to destroy all misleading and deceptive advertising materials and products.

G. An order requiring Defendants to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the UCL, FAL or CLRA, plus pre-and post-judgment interest thereon.

H. Costs, expenses, and reasonable attorneys' fees.

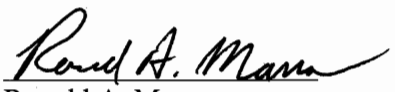
I. Any other and further relief the Court deems necessary, just, or proper.

JURY DEMAND

Plaintiff demands a trial by jury on all causes of action so triable.

DATED: June 14, 2011

Respectfully Submitted,



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Counsel for Plaintiff and the Proposed Classes

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Robert Reid, on behalf of himself and all others similarly situated

(b) County of Residence of First Listed Plaintiff San Diego
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Law Offices of Ronald A. Marron,
3636 4th Ave., Ste. 202, San Diego, CA 92103

DEFENDANTS

Johnson & Johnson, and McNeil Nutritionals, LLC

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

'11CV1310 L POR

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question (U.S. Government Not a Party)
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ❒ 365 Personal Injury - Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 444 Welfare
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 440 Other Civil Rights

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900Appeal of Fee Determination Under Equal Access to Justice
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district (specify) ❒ 6 Multidistrict Litigation ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
28 U.S.C. Section 1332(d)(2)

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☑ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
06/14/2011

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

Exhibit A

Benecol® Spread Tub – 5-Panel Packaging (Outside and Inside)

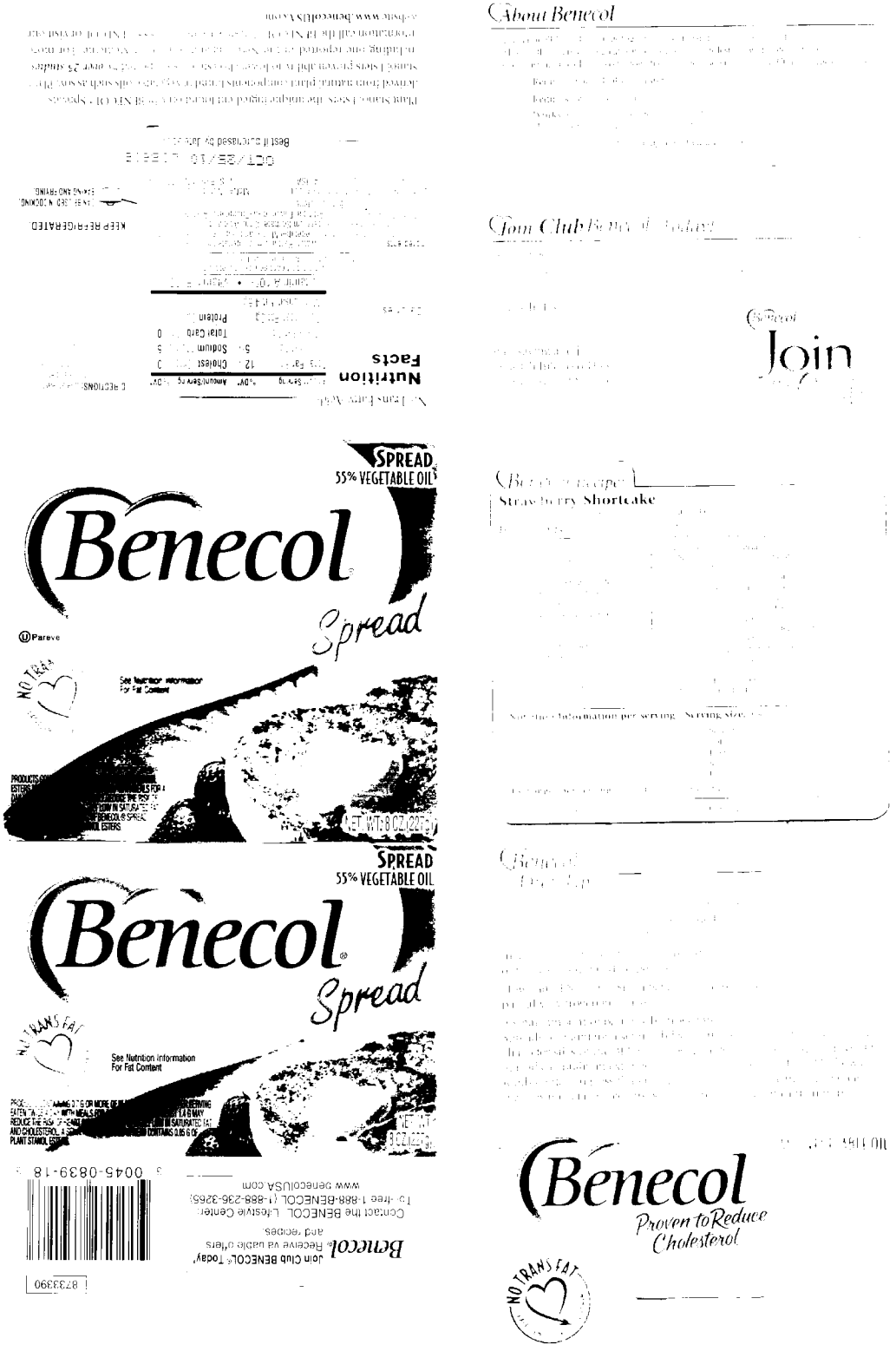
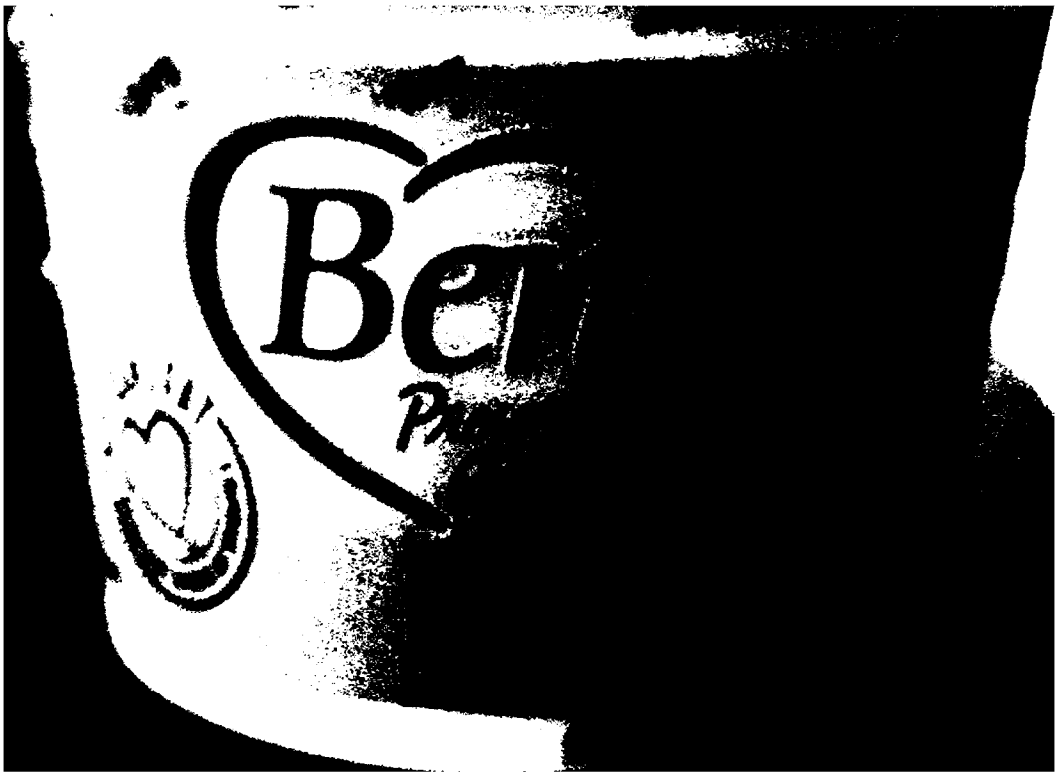
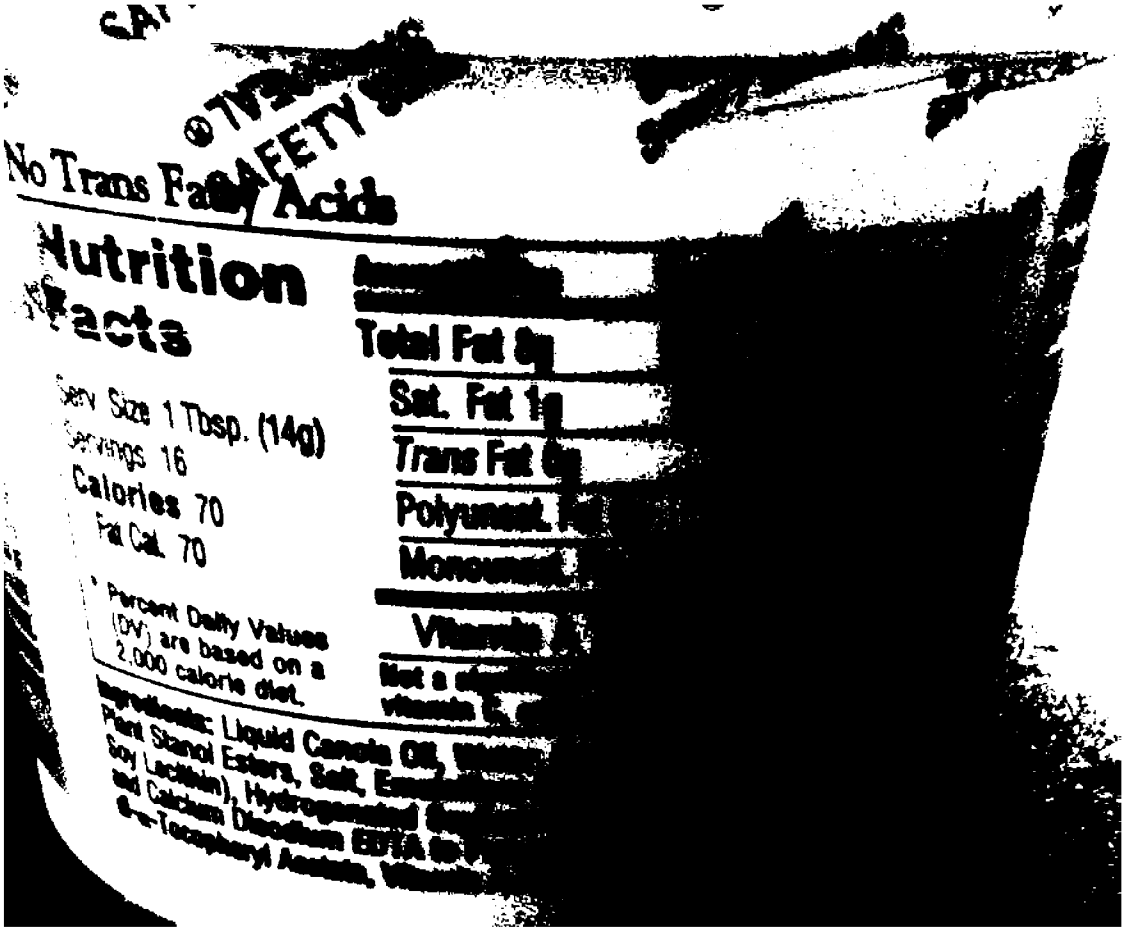


Exhibit B

Benecol® Spread Tub – Photos




No Trans Fatty Acids
Nutrition
Facts
Serv Size 1 Tbsp. (14g)
Servings 16
Calories 70
Fat Cal. 70
* Percent Daily Values (DV) are based on a 2,000 calorie diet.
Total Fat
Sat. Fat
Trans Fat
Polyunsat.
Monounsat.
Vitamin
Ingredients: Liquid Canola Oil,
Plant Stanol Esters, Salt,
Soy Lecithin), Hydrogenated
and Calcium Disodium EDTA
d-α-Tocopheryl Acetate,

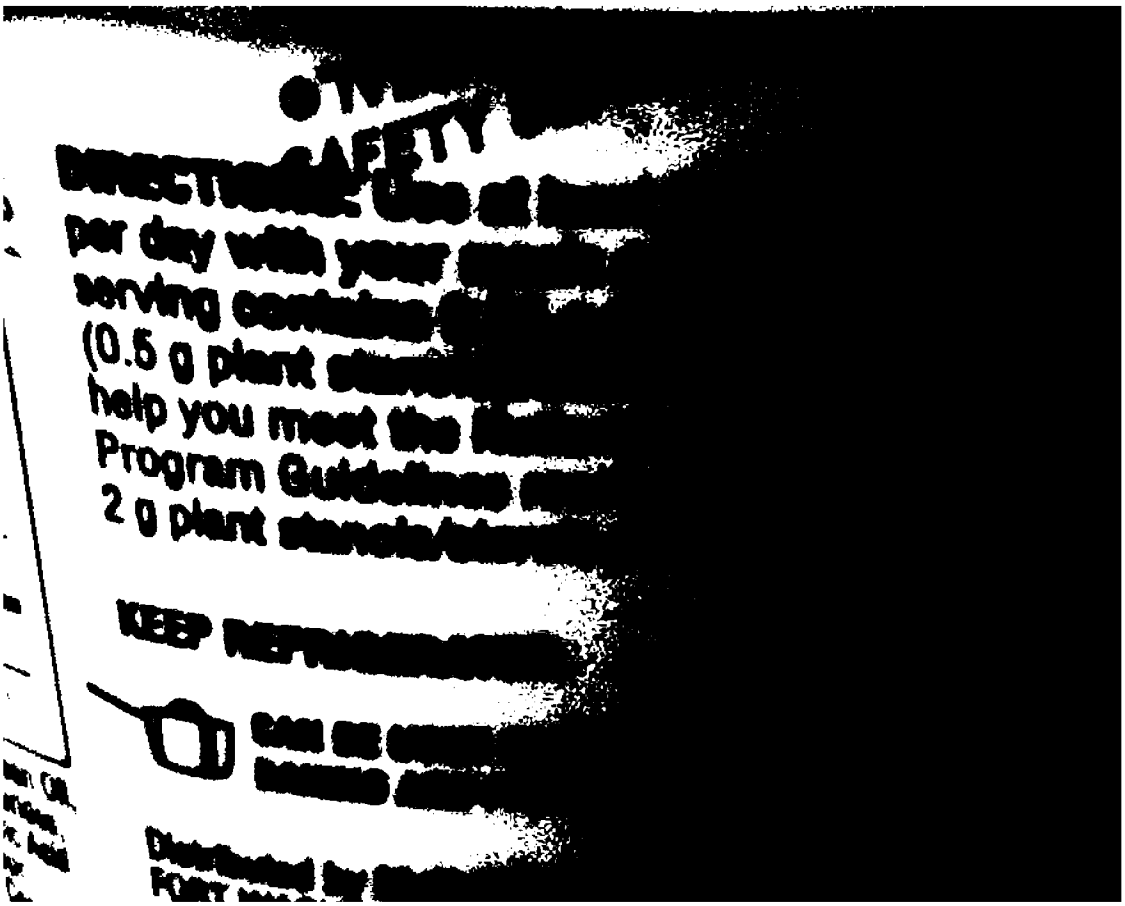
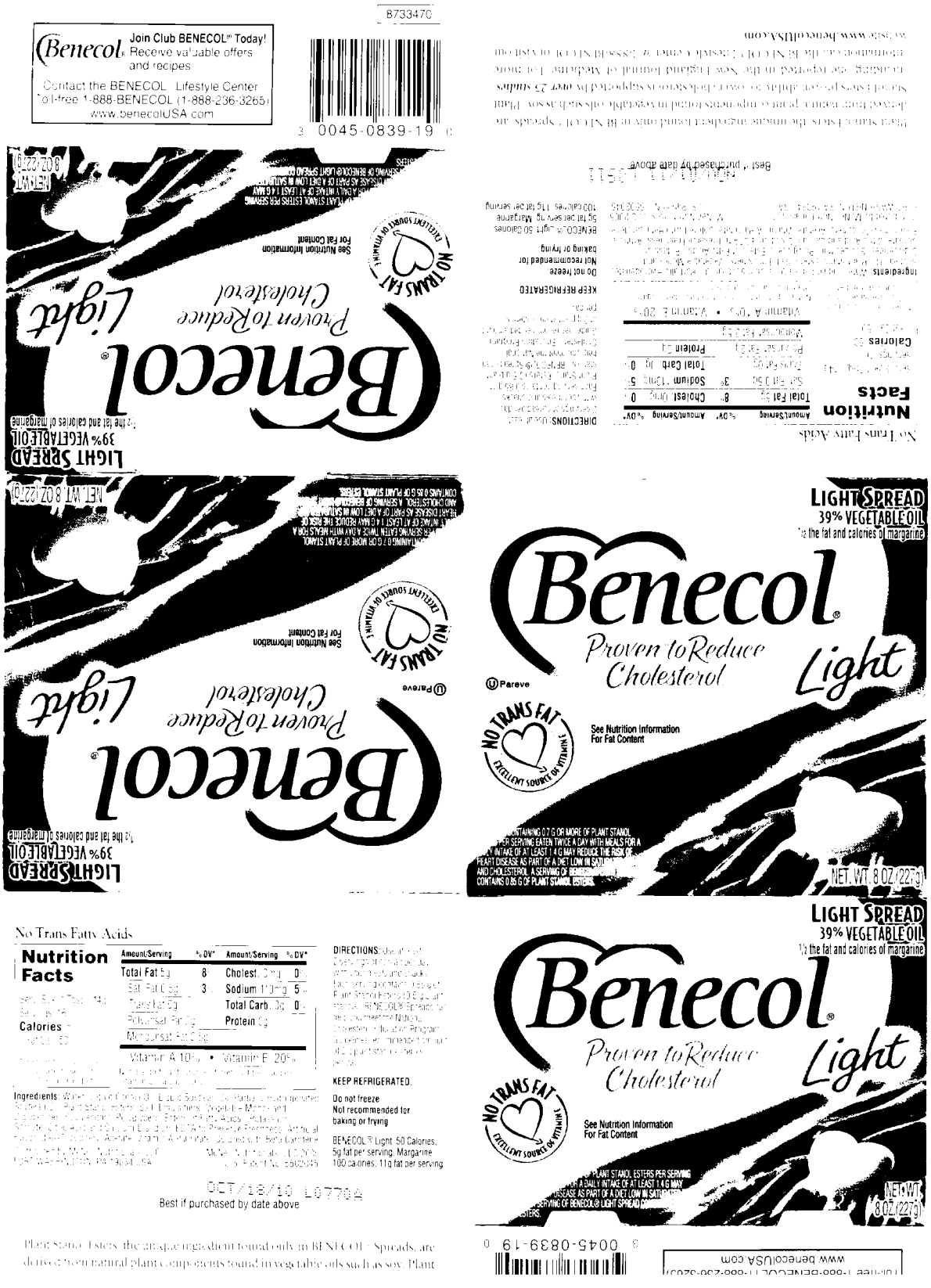

per day with your
serving contains
(0.5 g plant
help you meet the
Program Guidelines
2 g plant
KEEP REFRIGERATED
Distributed by

Exhibit C

Benecol® Light Spread Tub – 5-panel Packaging (Inside and Outside)



Join the Club

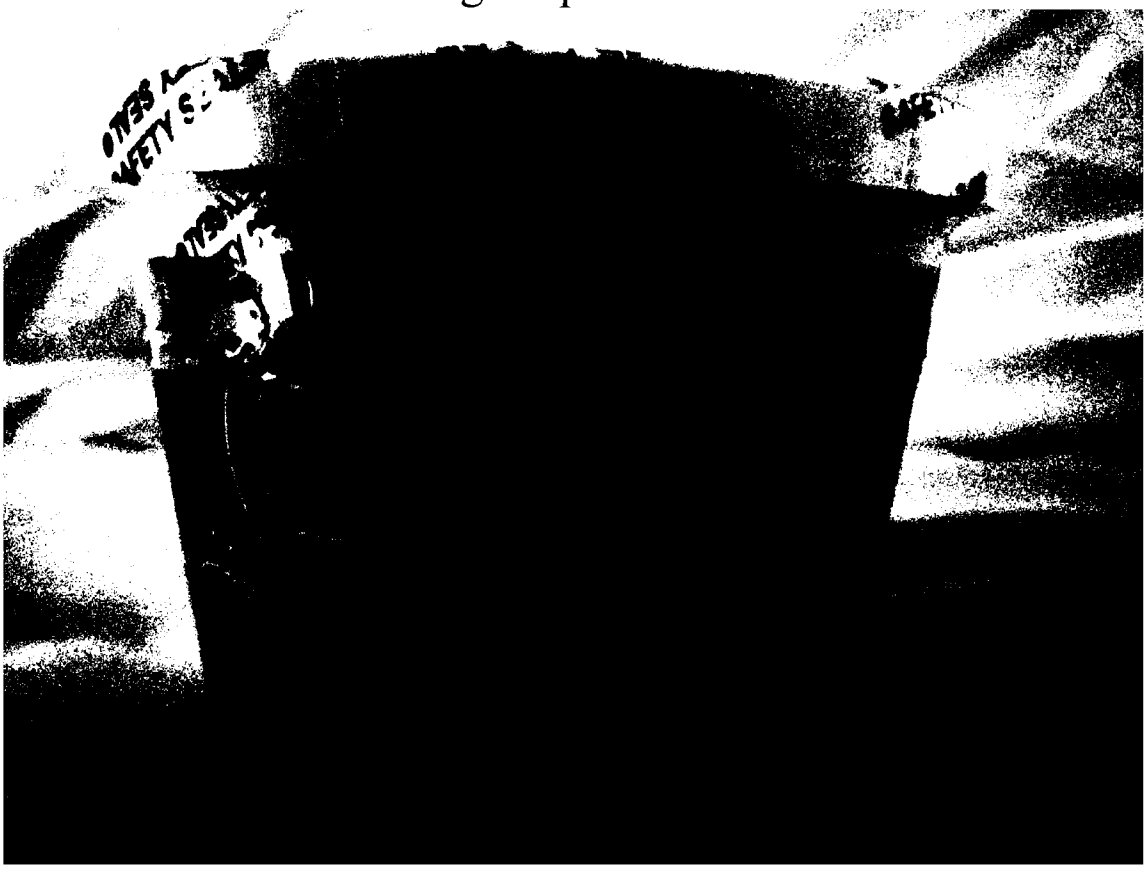
Benecol
Diet Tip

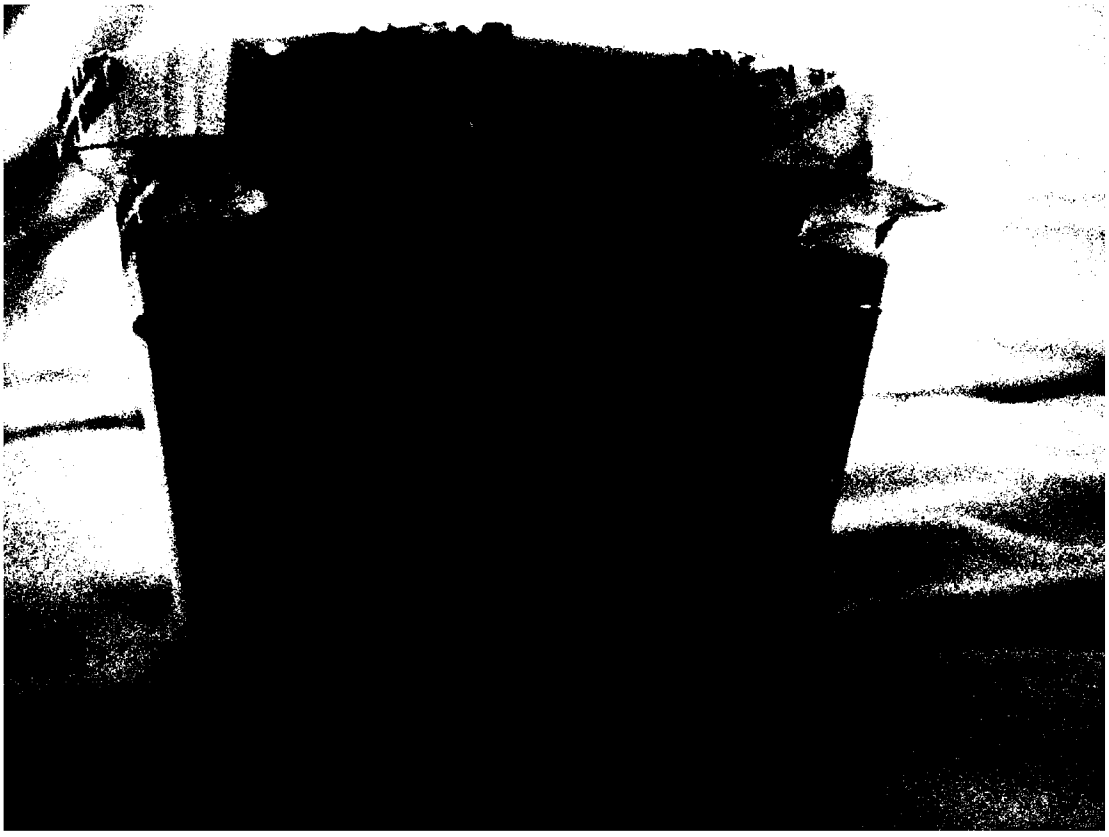
39% VEGETABLE OIL

Benecol
Proven to Reduce Cholesterol

Exhibit D

Benecol® Light Spread Tub – Photos





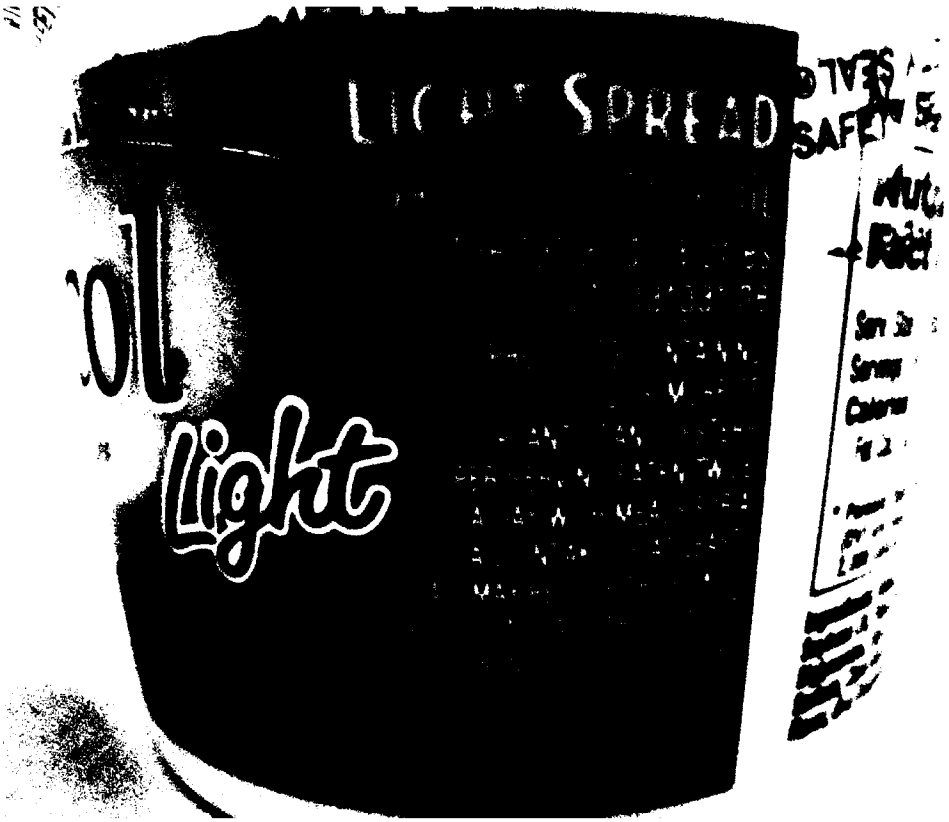

Light

Exhibit E

Physician Brochure

The Proven Benefits of BENECOL® Spread

As monotherapy

- Clinically proven to reduce LDL cholesterol levels up to 14%[2,5,6]

As adjunctive therapy

- In a randomized, double-blind, placebo-controlled trial involving patients on a statin who had not reached their LDL cholesterol goal... Adding BENECOL® Spread lowered LDL cholesterol by an additional 17% vs. only 7% in the placebo group ($P<0.0001$)[3]
- Starts lowering LDL cholesterol within 2 weeks[3]

All results above are based on 3 servings per day with meals in place of regular spread.

Benecol
Proven to Significantly Reduce Cholesterol

References

1. *ATP III Guidelines at-a-Glance Quick Desk Reference.* Bethesda, Md: National Institutes of Health; May 2001. NIH publication no. 01-3305.

2. Miettinen TA, Puska P, Gylling H, et al. Reduction of serum cholesterol with sitostanol ester margarine in a mildly hypercholesterolemic population. *N Engl J Med.* 1995;333:1308-1312.

3. Blair SN, Capuzzi DM, Gottlieb SO, et al. Incremental reduction of serum total cholesterol and low-density lipoprotein cholesterol with the addition of plant stanol ester-containing spread to statin therapy. *Am J Cardiol.* 2000;86(1):46-52.

4. *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) Executive Summary.* Bethesda, Md: National Institutes of Health; May 2001. NIH publication no. 01-3670.

5. Gylling H, Radhakrishnan R, Miettinen TA. Reduction of serum cholesterol in postmenopausal women with previous myocardial infarction and cholesterol malabsorption induced by dietary sitostanol ester margarine: women and dietary sitostanol. *Circulation.* 1997;96(12):4226-4231.

6. Hallikainen MA, Uusitupa MIJ. Effects of 2 low-fat stanol ester-containing margarines on serum cholesterol concentrations as part of a low-fat diet in hypercholesterolemic subjects. *Am J Clin Nutr.* 1999;69:403-410.

Managing Low-Density Lipoprotein (LDL) Cholesterol

Your Quick Guide to Therapeutic Lifestyle Changes (TLC) and the Role of BENECOL® Products

Based on recommendations of the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III)

Brought to you as a service of

McNeil Nutritionals

McNeil Nutritionals, Division of McNeil-PPC, Inc.

Some Key Aspects of the ATP III Guidelines for Your Patients with Elevated LDL Cholesterol[1]

The ATP III Guidelines provide physicians with a comprehensive, evidence-based plan for the management of patients with elevated cholesterol levels, particularly elevated LDL cholesterol—a major cause of coronary heart disease (CHD).

The ATP III Guidelines stress the importance of assessing risk factors for CHD. This assessment, done systematically, is built around some key steps.

Determine lipoprotein levels by obtaining a complete lipoprotein profile* following a 9- to 12- hour fast

Identify presence of clinical atherosclerotic disease that puts a patient at high risk for CHD events (CHD risk equivalent). These conditions include:

- Clinical CHD
- Symptomatic carotid artery disease
- Peripheral arterial disease
- Abdominal aortic aneurysm

Determine presence of major risk factors other than elevated LDL

- Cigarette smoking
- Hypertension (BP ≥ 140/90 mmHg or on antihypertensive medication)
- Low high-density lipoprotein (HDL) cholesterol (< 40 mg/dL)
- Family history of premature CHD†
- Age (men ≥ 45 years; women ≥ 55 years)

Note: in ATP III, diabetes is regarded as a CHD risk equivalent.

If 2+ risk factors (other than LDL) are present without CHD or CHD risk equivalent, assess 10-year (short-term) CHD risk. Three levels of 10-year risk:

- > 20% (CHD risk equivalent)
- 10-20%
- <10%

Determine risk category for a major coronary event:

- Establish LDL cholesterol goal
- Determine the LDL level at which to initiate Therapeutic Lifestyle Changes (TLC)
- Determine the LDL level at which to consider drug therapy

If risk category‡ is:	LDL cholesterol goal is:
CHD or CHD risk equivalents§ (10-year risk > 20%)	<100 mg/dL
2 + risk factors (10-year risk ≤ 20%)	<130 mg/dL
0-1 risk factor	<160 mg/dL

If LDL cholesterol is above goal, the ATP III Guidelines recommend initiating Therapeutic Lifestyle Changes (TLC)

- TLC is a multifaceted approach that calls for:
- Reducing intake of saturated fats (<7% of daily calories) and cholesterol (<200 mg/day)
- Consuming plant stanols or sterols (2 g/day)
- Increasing soluble fiber (10-25 g/day)
- Reducing weight
- Increasing physical activity

The following pages provide a schematic illustrating how TLC is incorporated into the ATP III Guidelines, and how BENECOL® Spread can be included as part of TLC

- Plant stanol ester, found only in BENECOL® Products, can be included as part of TLC
- The efficacy and safety of plant stanol esters have been documented in more than 25 scientific studies published in peer-reviewed journals, including *The New England Journal of Medicine* and *The American Journal of Cardiology*[2,3]

*Assessments include LDL cholesterol (mg/dL) from <100 (optimal) to ≥190 (very high), total cholesterol (mg/dL) from < 200 (desirable) to ≥ 240 (high), and HDL cholesterol (mg/dL) from < 40 (low) to ≥ 60 (high). †CHD in first-degree male relative <55 years and/or in first-degree female relative <65 years. ‡In the three risk categories, the LDL level at which to initiate TLC is ≥100, ≥130, and ≥160 mg/dL, respectively. The LDL level at which to consider drug therapy is ≥130 mg/dL in category 1, ≥130 mg/dL (10-year risk 10-20%) or ≥160 mg/dL (10-year risk <10%) in category 2, and ≥190 mg/dL in category 3. Almost all people with a 0-1 risk factor have a 10-year risk <10%; consequently, a 10-year risk assessment in such people is not necessary. §CHD risk equivalents include other clinical forms of atherosclerotic disease and diabetes.

A Step-by-Step Model for TLC Management of LDL Cholesterol[4]

A model that includes an important role for plant stanol ester in the form of BENECOL® Spread

Visit 1

Begin lifestyle therapies.

- Emphasize reduction in saturated fat and cholesterol
- Encourage moderate physical activity
- Consider referral to dietitian

6 weeks

Visit 2

Evaluate LDL cholesterol response. If LDL goal not achieved, intensify LDL cholesterol-lowering therapy.

- Reinforce reduction in saturated fat and cholesterol
- Consider adding plant stanols/sterols
- Increase fiber intake
- Consider referral to dietitian

Consider adding BENECOL® Spread (2-3 servings daily)*

* 1 serving=1 tablespoon of BENECOL® Spread

6 weeks

Visit 3

Evaluate LDL cholesterol response. If LDL goal not achieved, consider adding drug therapy.

- Initiate therapy for metabolic syndrome
- Intensify weight management and physical activity
- Consider referral to dietitian

Maintain use of BENECOL® Spread (2-3 servings daily)*

Every 4 to 6 months

Follow-up visits

Monitor adherence to TLC.

Please note: A portion of the population whose short- or long-term risk for CHD is high will require LDL-lowering drugs in addition to TLC to reach the designated goal for LDL cholesterol. When drugs are prescribed, attention to TLC should always be maintained and reinforced.

Adapted from ATP III Guidelines, Executive Summary[4]