IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

JENNY CRAIG, individually and on behalf of all others similarly situated, PLAINTIFF

v. Case No. 5:14-cv-05214-TLB

TWININGS NORTH AMERICA, INC., DEFENDANT

MOTION TO RECONSIDER ORDER OF FEBRUARY 5, 2015 AND ENTRY OF JUDGMENT

Plaintiff Jenny Craig respectfully moves, pursuant to Federal Rules of Civil Procedure 59(e) and 60(b), for reconsideration of this Court's Order of February 5, 2015, granting Defendants' Motion to Dismiss Plaintiff's First Amended Complaint with prejudice (Dkt. #29) and further moves for an Order withdrawing the Judgment entered February 5, 2015. (Dkt. #30).

1. This Motion is brought pursuant to (1) Federal Rule 59(e), which allows the Court to correct errors of law or fact upon which the judgment is based and to prevent manifest injustice; and (2) Federal Rule 60(b), which allows the Court to correct mistakes or simply because other reasons justify relief. In particular, the Plaintiff seeks reconsideration of the Court's decision that Twinings' "natural source" claim on its label was not a nutrient content claim and therefore, Plaintiff's claims were beyond the scope of the Federal Regulations and therefore preempted, which also dictated the remaining decisions of the Court.

2. In support of Plaintiff's Motion to Reconsider, Plaintiff submits the following:

(a) Sprouts FDA Warning Letter, Exhibit "1;"

(b) Sprouts Close Out Letter, Exhibit "2;" and

(c) Declaration of Ed Scarbrough, Exhibit "3."

WHEREFORE, Plaintiff respectfully submits that reconsideration of the Order granting the Motion to Dismiss and Judgment is appropriate.

Dated: March 5, 2015

Respectfully submitted,

/s/ Kenneth R. Shemin
Kenneth R. Shemin, ABA No. 78138
SHEMIN LAW FIRM, PLLC
3333 Pinnacle Hills Parkway, Suite 603
Rogers, AR 72758
Telephone: (479) 845-3305
Facsimile: (479) 845-2198

/s/ Thomas P. Thrash
Thomas P. Thrash (ABA No. 80147)
Marcus Neil Bozeman (ABA No. 95287)
THRASH LAW FIRM, P.A.
1101 Garland Street
Little Rock, AR 72201
Telephone: (501) 374-1058
Facsimile: (501) 374-2222

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, Kenneth R. Shemin, the undersigned, hereby certify that on March 5, 2015, a true and correct copy of the foregoing will be served by electronic mail and electronic notification through the District Court CM/ECF electronic filing system upon the following counsel of record:

Kevin A. Crass
R. Christopher Lawson
Friday, Eldredge & Clark, LLP
400 W. Capitol Ave., Suite 2000
Little Rock, AR 72201-3522

David L. Wallace
Michael R. Kelly
HERBERT SMITH FREEHILS NEW YORK, LLP
450 Lexington Ave., 14th Floor
New York, NY 10017

/s/ Kenneth R. Shemin
Kenneth R. Shemin

EXHIBIT 1

Inspections, Compliance, Enforcement, and Criminal Investigations

Jonathan's Sprouts Inc. 3/24/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

WARNING LETTER
NWE-13-11W

VIA UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

March 24, 2011

Mr. Robert Sanderson
Owner
Jonathan's Sprouts Inc.
384 Vaughan Hill Road
Rochester, MA 02770

Dear Mr. Sanderson:

The United States Food and Drug Administration (FDA) conducted an inspection of your facility located at 384 Vaughan Hill Road, Rochester, MA, from September 27, 2010 to October 13, 2010. The inspection determined that your firm is a manufacturer and distributor of sprouts. During the inspection, our investigators collected sample labels for your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts. The FDA reviewed your website at http://www.jonathansorganic.com[1], in February 2011 and determined that this website constitutes labeling under section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act) because the website address appears on the label of your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts. Based on our review of your product labels and website, your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] and are misbranded within the meaning of section 403 of the Act [21 U.S.C. § 343]. Regulations implementing the food labeling requirements of the Act can be found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and implementing regulations through

links on FDA's Internet home page at http://www.fda.gov[2].

Unapproved New Drug

Your website address www.jonathansorganic.com[3] appears on your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts and Organic Broccoli Sprouts product labels. We have reviewed your website in February 2011 and have determined that your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts and Organic Broccoli Sprouts products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment or prevention of disease. The marketing of these products with these claims violates the Act. Examples of some of the claims observed on your website from the webpage entitled "Sprouts, The Miracle Food! - Rich Vitamins, Minerals and Phytochemicals" and in a brochure entitled "Health Benefits of Sprouts" that can be viewed and downloaded from your website include, but are not limited to the following:

- "[S]prouts are full of phytochemicals . . . that are powerful allies in protecting us from the growth of cancer cells . . . in lowering cholesterol levels . . . ."
- "Mung Bean Sprouts Identified as Potent Anti-tumor Agent"
- "Studies on canavanine . . . in alfalfa, have demonstrated benefit for pancreatic, colon and leukemia cancers."
- "Alfalfa Sprouts High in Cholesterol Lowering Agent"
- "Saponins [substance found in alfalfa sprouts] lower the bad cholesterol . . . . Animal studies prove their benefit in arteriosclerosis and cardiovascular disease."
- "Phytoestrogens [substance in alfalfa, clover, and mung bean sprouts] . . . prevent . . . osteoporosis. They are also helpful in controlling . . . fibrocystic breast tumors."
- "Research into the possible benefits of phytoestrogens has focused on . . . a) Cancer-breast and prostate in particular . . . c) Osteoporosis d) Heart disease (antioxidant activity) Other potential areas of benefit include diabetes . . . ."
- "The cruciferous sprouts: Broccoli, [lists others] . . . Cancer Fighters"
- "Broccoli . . . may fight cancer."
- "Broccoli sprouts are rich in one class of cancer protecting agents."
- "There is strong evidence that just two or three tablespoons of broccoli sprouts a day can help prevent cancer, gastric cancer, and other diseases."
- "[S]ulforaphane [obtained from a substance in broccoli] prevents tumor growth and kills stomach bacteria that lead to ulcers and stomach cancer. In one study, they showed that feeding broccoli sprouts to rats prevented . . . heart disease, and stroke."

These products are not generally recognized as safe and effective for the above referenced uses; therefore these products are "new drugs" under section 201(p) of the Act [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 section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, your products are offere

for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; hence adequate directions cannot be written so a layman can use them safely for their intended uses. Therefore, your products are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)]

Unauthorized Health Claims

Your Organic Alfalfa Sprouts, Organic Mung Bean Sprouts and Organic Clover Sprouts products are misbranded within the meaning of 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because the labeling bears unauthorized health claims. Your website is referenced on each of the above product labels and was found to contain the following unauthorized health claims on the webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals":

- "[P]hytoestrogens [substance found in alfalfa, clover, and mung bean sprouts] . . . may have desirable effects, for example reduce the risk of breast cancer."

- "Phytoestrogens actually reduce the risk of breast cancer."

These health claims misbrand the products listed above because these health claims have not been authorized either by regulation [see section 403(r)(3)(A)-(B) of the Act [21 U.S.C. § 343(r)(3)(A)-(B)]] or under authority of the health claim notification provision of the Act [see section 403(r)(3)(C) of the Act [2: U.S.C. § 343(r)(3)(C)]]. FDA has not authorized any health claims for phytoestrogens.

Unauthorized Nutrient Content Claims

Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Mung Bean Sprouts, and Organic Clover Sprouts products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r (1)(A)] because the product labels bear nutrient content claims that are not authorized by regulation or fa to meet the terms of authorizing regulations. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient of a type required to be in the labeling misbrands a product under section 403(r)(1)(A) of the Act. Specifically,

1. Your product labels and labeling bear antioxidant nutrient content claims but fail to comply with the requirements for using such a claim. Nutrient content claims using the term "antioxidant" must comply with, among other requirements, the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a reference daily intake (RDI) must have been established for each of the nutrients that are the subject of the claim [21 CFR 101.54(g)(1)], and these nutrients must have recognized antioxidant activity [21 CFR 101.54(g)(2)]. The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) [21 CFR 101.54(g)(3)]. For example, to bear the claim "high in antioxidant vitamin C," the product must contain 2(percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity [21 CFR 101.54(g)(4)]. The antioxidant claims found in your product labeling are nutrient content claims because they characterize the level of antioxidants in your product, but they do not comply with 21 CFR 101.54(g)(4) because they do not include the names of the nutrients that are the subject of the claim or link the nutrients with the claim by use of a symbol. This includes the following claims:

- On your website on the page entitled "Tasty, Nutritious Sprout Recipes: Index": "All Sprouts are . . . HIGH IN ANTIOXIDANTS."

- On your website on the page entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals": "Sprouts also contain an abundance of highly active antioxidants . . . ."

2. In accordance with 21 CFR 101.54(b), the terms "high," "rich in," or "excellent source of" may be used to characterize the level of a nutrient on the label and in the labeling of foods provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC). Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products do not meet the requirements to make certain "high" claims that appear in your product labeling. Specifically:

The webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" found on your website bears the claim "Sprouts . . . Rich in Vitamins, Minerals . . ." However, as stated on your nutrition facts panels, your Organic Alfalfa Sprouts and Organic Clover Sprouts products both contain only 2 percent of the Reference Daily Intake (RDI) for vitamin A and calcium, 10 percent of the RDI for vitamin C, and 4 percent of the RDI for iron. Neither of these products contains vitamins or minerals at levels that are 20 percent or more of the RDI. In addition, as stated on your nutrition facts panels, your Organic Broccoli Sprouts contain 10 percent of the RDI for vitamin A, 60 percent of the RDI for vitamin C, 6 percent of the RDI for Calcium, and 4 percent of the RDI for Iron. Your Organic Mung Bean Sprouts contai 4 percent of the RDI for vitamin A, 20 percent of the RDI for vitamin C, 2 percent of the RDI for Calcium, and 4 percent of the RDI for Iron. Neither of these products contain minerals at 20 percent or more of the RDI.

Although your labels do state that your Organic Broccoli Sprouts and Organic Mung Bean Sprouts contain 20 percent or more of the RDI for vitamin C, the claim uses the plural "Vitamins," implying that more than one vitamin should be present at levels of 20 percent or more of the RDI. Therefore your Organic Alfalfa Sprouts, Organic Clover Sprouts, Organic Broccoli Sprouts, and Organic Mung Bean Sprouts products do not meet the requirements to make "rich in" claims for vitamins and minerals.

- Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Clover Sprouts High in Phytoestrogens[.]" This claim characterizes the level of nutrients of the type required to be in nutrition labeling (phytoestrogens) in your products by use of the defined term "high." However, because there is no established RDI or DRV fo phytoestrogens, this claim does not comply with the requirements for use of the term "high" in 21 CFR 101.54(b).

3. In accordance with 21 CFR 101.54(c), the term "good source" may be used to characterize the level of a nutrient on the label and in the labeling of foods provided that the food contains 10 to 19 percent of the RDI or the DRV per RACC. Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products do not meet the requirements to make the following "good source" claim that appears in your product labeling.

- Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the nutrient content claim: "They [all sprouts] provide a good source of . . . calcium . . . as well as fiber, iron . . . ." However, as stated on your nutrition facts panels for your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts these products fail to contain at least 10 percent of the RDI for calcium and iron. All of these products, with the exception of your Organic Broccoli Sprouts product, also fail to meet the requirement to bear a good source of fiber claim because, as stated on your nutrition facts panels, they fail to contain at least 10 percent of the DRV for dietary fiber.

4. Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the nutrient content claim "They [all sprouts] provide a good source of vitamins B . . . and K, phosphorus . . . potassium . . . and thiamin." However, Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products product labels fail to provide information about the levels of vitamin B, vitamin K, phosphorus, potassium, and thiamin in those products as required under 21 CFR 101.9(c)(8)(ii), 101.9(c)(5), and 101.13(n). Therefore, these products are misbranded under section 403(q) and 403(r)(1)(A) of the Act. Further, because the nutrient levels are not declared, it is not clear whether the product

have the required minimum 10 percent of the RDI or DRV per RACC of these nutrients as required under 21 CFR 101.54(c) for use of the defined term "good source."

5. In accordance with 21 CFR 101.65(c)(2), the phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz. glass of orange juice."). Your products fail to meet the requirements to make this type of implied nutrient content claim, which is contained in your product labeling. Specifically:

- Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the implied nutrient content claim: "one-half cup of almost any sprouted seec provides as much Vitamin C as six glasses of orange juice." According to your product labels one 85 g serving is equal to a cup of sprouts; therefore, one half of a labeled serving would equal a half cup As stated on your nutrition facts panels, one half serving of your Organic Alfalfa Sprouts contains 5 percent of the RDI of Vitamin C, one half serving of your Organic Broccoli Sprouts contains 30 percent of the RDI of Vitamin C, one half serving of your Organic Clover Sprouts contains 5 percent of the RDI of Vitamin C, and one half serving of your Organic Mung Bean Sprouts contains 10 percer of the RDI of Vitamin C. However, based on the USDA National Nutrient Database,one 8 oz. serving of raw orange juice contains 124 mg of Vitamin C, which is over 200 percent of the RDI. Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Clover Sprouts, and Organic Mung Bean Sprouts do not contain as much Vitamin C as a single 8 oz. serving of orange juice and, by extension, do not contain as much Vitamin C as six 8 oz. glasses of orange juice; therefore, these products do not meet the requirements to make this claim.

- Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the implied nutrient content claim: "By weight, most sprouts contain twice the protein of meat." Your product labels declare an 8 gram serving size. As stated on your nutrition facts panels, 85 grams of your Organic Alfalfa Sprouts contains 3 grams of protein, 85 grams of your Organic Broccoli Sprouts contains 2 grams of protein, 85 grams of your Organic Clover Sprouts contains 3 grams of protein, and 85 grams of your Organic Mung Bean Sprouts contains 3 grams of protein. However, based on the USDA National Nutrient Database, an 85 gram serving of chicken tenders cooked in a conventional oven contains 13.41 grams of protein; an 85 gram serving of beef, bottom sirloin, tri-tip roast, separable lean and fat, trimmed to 0" fat, choice, cooked, roasted contains 21.81 grams of protein; and an 85 gram serving of pork, fresh, loin, sirloin (roasts), boneless, separable lean and fat, cooked, roasted contains 24.22 grams of protein. Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Clover Sprouts, and Organic Mung Bean Sprouts do not contain as much protein by weight as chicken, beef or pork, and, by extension, do not contain twice the protein by weight of chicken, beef or pork. Therefore, your products do not meet the requirements to make this claim.

6. In accordance with 21 CFR 101.61(b)(1)(i), the term "sodium free" may be used on the label or in the labeling of foods provided that the food contains less than 5 mg of sodium per RACC and per labeled serving. The webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the claim "Sprouts are sodium free." Your Organic Broccoli Sprouts contain 25 mg of sodium per 85 g labeled serving as declared on your nutrition facts panel; therefore, it does not meet the requirements to make a "sodium free" claim.

7. Your Organic Clover Sprouts product label bears the claim "Phytoestrogen Source[.]" Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Alfalfa sprouts are one of our finest food sources of . . . saponin." These claims are nutrient content claim subject to section 403(r)(1)(A) of the Act because they characterize the level of nutrients of a type required to be in nutrition labeling (phytoestrogen and saponin) in your products by use of the term "source." Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization "source" by regulation. Therefore, this characterization may not be used in nutrient content claims.

We acknowledge your firm's efforts in addressing the issues raised in the FDA-483 Inspectional

Observations that was issued to you on October 13, 2010 and the specific corrections your letter indicates that you have made. Your corrective actions will be further evaluated during our next inspection of your facility and your response will be filed as a part of the inspectional record for this facility. The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your sprout products are labeled and processed in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also have the following comments about your product labels:

Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts are single ingredient foods and therefore are not required to bear an ingredients declaration under section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)]. You have elected to provide ingredients statements on these products. Your ingredients statements on each of these products declare the corresponding type of seed (i.e. "Contents: Organic Alfalfa Seeds"). However, as required by section 403(i)(2) of the Act, your ingredient declaration must use the food's common or usual name, which is the name of the specific kind of sprout (i.e., "Contents: Alfalfa Sprouts").

Your Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts product labels contain the statements "Certified Organic by QAI," and "Product of USA" on the information panel between the name and place of business and ingredients statement. However, 21 CFR 101.2(e) requires that all required information appearing on the information panel shall appear in one place without intervening material.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Attention: Lori A. Holmquist, Compliance Officer, 330 Civic Center Drive, Suite 1, Box 4, Augusta, Maine 04330. If you have questions regarding any issues in this letter, please contact Ms. Holmquist at 207.622.8268 x13.

Sincerely,

/S/

Mutahar S. Shamsi

District Director

New England District

Close Out Letter

- Jonathan's Sprouts Inc - Close Out Letter 6/22/11[4] [ARCHIVED]

Page Last Updated: 06/23/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Links on this page:

1. http://www.jonathansorganic.com
2. http://www.fda.gov
3. http://www.jonathansorganic.com
4. /ICECI/EnforcementActions/WarningLetters/2011/ucm260559.htm

EXHIBIT 2

Inspections, Compliance, Enforcement, and Criminal Investigations

Jonathan's Sprouts Inc - Close Out Letter 6/22/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

June 22, 2011

Mr. Robert Sanderson
Owner
Jonathan's Sprouts Inc.
384 Vaughan Hill Road
Rochester, MA 02770

Dear Mr. Sanderson:

The Food and Drug Administration has completed an evaluation of your firm's corrective actions in response to our Warning Letter NWE-13-11W. Based on our evaluation, it appears that you have addressed the violations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

/s/

Lori A. Holmquist
Compliance Officer
New England District Office
Augusta Maine Resident Post

Page Last Updated: 06/23/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

EXHIBIT 3

DECLARATION OF F. EDWARD SCARBROUGH

I, F. Edward Scarbrough, declare and state:

1. In 1971, I received my Ph.D. in Chemistry from Harvard University where my doctoral thesis was advanced under the direction of Nobel Laureate Professor William N. Lipscomb. In 1976, I began working for the Food and Drug Administration ("FDA") as a Chemist in the Division of Food and Color Additives. Working up the chain of command at the FDA, in 1990, I became the Director, Office of Food Labeling. As the Director, I was responsible for planning, organizing, staffing, coordinating, and managing all regulatory programs, research projects, and other activities related to the labeling of food within the United States. These responsibilities included directing the activities necessary to implement the Nutrition Labeling and Education Act of 1990, which required labeling on virtually all processed foods sold in the U.S. As part of that goal, the office that I directed created the "Nutrition Facts" label. Since 2008, I have been self-employed as a consultant with Scarbrough Consultants, LLC.

2. Attached hereto as Exhibit A is my curriculum vitae, which includes a list of publications I have authored related to food labeling and other publications within the previous 10 years.

3. For this case, I am being compensated at a rate of $250.00 per hour.

4. In preparing this declaration, I have relied on my education and work history as well as the labels at issue.

5. The Nutrition Labeling and Education Act of 1990 ("NLEA"), enacted on November 8, 1990, amended several sections of the Food, Drug and Cosmetic Act, including the misbranding requirements, stating that virtually all packaged foods sold in the United States

would be misbranded if the label did not contain nutrition labeling[1]. Equally important, the NLEA also stated that a food was misbranded if a claim was made on the label, or in labeling, that was not in accordance with regulations promulgated by FDA (through a delegation of authority by the Secretary of Health and Human Services).

http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm#GUIDE%20FOR%20REVIEW%20OF%20NUTRITION

6. As Director of the Office of Food Labeling, I was tasked by the Commissioner of Food and Drugs, Dr. David Kessler, to form an interdisciplinary team of approximately 30 individuals, drawn from units throughout FDA, to focus solely on developing the proposed and final regulations required by NLEA. On November 27, 1991, FDA issued more than 20 proposed regulations to implement NLEA, drafted by the team that I had formed and directed. In response to the proposed regulations, FDA received approximately 4000 comments from interested parties, including consumers, the food industry, academicians and foreign governments. The labeling team was then responsible for drafting final regulations that addressed all comments received, either by incorporating recommendations in the comment into the final regulations or explaining why the agency was not accepting that particular comment. On January 6, 1993, FDA issued the final regulations implementing the requirements of NLEA.

7. The policies and practices of FDA are those of close and frequent communication with the food industry. For example, FDA encouraged meetings with the industry to explain appropriate interpretations of regulations and current agency thinking. In addition to regulations,

[1] The NLEA made exemptions for foods of insignificant nutritional value and for very small businesses, with a definition of small business, based on employees and units sold, contained within the law. However, any product with a nutrition-related label claim, regardless of nutritional value or size of the business, must provide nutrition labeling and the claim must be made in accordance with FDA regulations.

FDA periodically publishes guidance documents, which provide agency thinking on policies and regulations. FDA also issues warning letters to firms that have labels or labeling that the agency considers to be in violation of agency regulations. Warning letters are made public, posted on FDA's website. Guidance documents and warning letters represent FDA's interpretation of the regulation(s) and how the agency believes that the regulation(s) should be complied with. Therefore the food industry should be well aware of FDA regulations and policies.

8. However, it is important to stress that because a product is on the market with a non-complying label does not mean that FDA has determined that the non-compliance is insignificant and can be accepted in the food supply. On the contrary, FDA has limited resources and a multitude of competing priorities. Within those limitations, situations which may bring immediate physical harm to consumers must be addressed immediately; whereas with issues such as nutrition claims, the consequences to public health could be just as, or more, important, but the effects are more long-term.

9. I have been asked to comment on the claim "*Natural Source of Antioxidants*" that appears on the label of a number of Twinings' products (e.g. Twinings Green Tea). It is my opinion that this claim causes the food to be misbranded in a number of ways. As discussed more fully below, I believe that: (1) The term "*source*" characterizes the level of a nutrient in a food and must be provided for in FDA regulations, which it is not; (2) The use of the term "antioxidants" without specifying the antioxidants being referenced violates FDA regulations and policy; and (3) The antioxidants found in green tea do not have a RDI (Reference Daily Intake) and therefore cannot be the subject of a claim that characterizes the level of a nutrient. I base this opinion on my work experience at FDA as well as FDA regulations, guidance and warning letters.

10. On November 27, 1991, FDA proposed regulations implementing the requirements of the NLEA. Section 403(q)(5)(C) of the NLEA exempted foods that contain insignificant amounts of nutrients from the nutrition labeling requirements. For example, this exemption would apply to certain single ingredient foods, such as coffee, that contain less than 2% per serving of any nutrient required to be listed in the "Nutrition Facts" panel. However, the act explicitly states that the exemption applies only "if the label, labeling or advertising of such food does not make any claim with respect to the nutritional value of such food." In the preamble to the proposed regulations, FDA reiterated this provision of the NLEA, stating that the exemption is available "only when there are no nutrition claims in the label, labeling or advertising for the food."[2] The claim "*Natural Source of Antioxidants*" is a nutrition claim on the label of the Twinings' products at issue in this case. Accordingly, these products are subject to FDA's nutrition labeling requirements. Further, all nutrition claims on foods regulated by FDA are subject to the nutrition claims regulations, regardless of nutrition insignificance or size of business.

11. In implementing the NLEA, FDA proposed that to be considered a "source" of a nutrient a food must contain 10 to 19 percent of the RDI for that nutrient per serving and that "good source" was a synonym for "source".[3] Therefore, in my opinion, FDA clearly considered, and still considers, that the term "source" characterizes the level of a nutrient in a food. In response to the proposals, the agency received a number of comments that contended that FDA should not define "source" because consumers cannot reasonably be expected to distinguish between foods that are "high" in a nutrient (20% or greater of the RDI per serving) as opposed to foods that are a "source" of a nutrient (10 to 19% of the RDI per serving). Comments also

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[2] Page 60376, Federal Register I Vol. 56 No. 229 / Wednesday, November 27 1991 I Proposed Rules
[3] Page 60471, Federal Register I Vol. 56 No. 229 / Wednesday, November 27 1991 I Proposed Rules

pointed out that FDA had proposed to allow claims such as "trivial source", negligible source" and "dietarily insignificant source" as synonyms for "free" and "low source of" as a synonym for "low" and that the use of the unmodified term "source" could be confusing to consumers. Therefore, the agency concluded that the use of the term "source" alone, although characterizing a level of a nutrient, did not allow consumers to make conclusions about the level of that nutrient present in a serving. In the final regulations, FDA retained the definition for "high" but replaced the term "source" with "good source".[4] It is my opinion, based on my work experience, that in all of the discussions during the development of the proposed and final regulations, the term "source" was considered by FDA to characterize the level of a nutrient in a food. Further, because FDA did not define "source" in a regulation, as required by the NLEA, the use of the unmodified term is not permitted and such use causes a food to be misbranded. [In the case of Twinings, the use of the modifier "natural" is, in my opinion, little more than marketing puffery and does not change my conclusions about the term "source".]

12. The use of the term "antioxidants" in the label statement "Natural Source of Antioxidants" on the Twinings products violates FDA regulations. Although antioxidant claims are allowed by FDA on food labels, they can only be made for antioxidant nutrients for which FDA has established a Reference Daily Intake (RDI). This requirement is clearly stated in FDA regulation 21 CFR 101.54(g)(1). Nutrients for which FDA has established a RDI are listed in 21 CFR 101.9. FDA established this requirement because the agency considered it important for there to be a "yardstick" against which to measure the claim. Otherwise, claims such as "source" could be made for products which provide physiologically insignificant amounts of the specified nutrient. FDA has not established a RDI for antioxidants found in tea. Therefore, any nutrient

[4] Federal Register / Vol. 58, No. 3 / Wednesday, January 6, 1993 / Rules and Regulations

content claim about antioxidants found in green tea on the labels of these foods causes the products to be misbranded and, therefore, illegal.

13. The label statement "Natural Source of Antioxidants" further causes the food to be misbranded because the label fails to identify the antioxidant(s) being referred to, as required by FDA regulation 21 C.F.R. § 101.54(g). The requirements for making antioxidant claims are also addressed in FDA guidance published in 2008: Guidance for Industry: Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Small Entity Compliance Guide.[5] FDA has also issued numerous warning letters directly addressing products similar to the Twinings' products that make claims similar to the claims being made on the Twinings labels. For example, in February 2010, FDA issued a warning letter to Fleminger Inc., Doing Business as Dr. Lee's TeaForHealth™ for TeaForHealth™ green tea products: Dr. Lee's TeaForHealth® 710EGCG™ inabottle™ Green Tea and Tea For Health® 710EGCG™ Ready-To-Drink Natural Brewed Green Tea, stating that the claim "Drink high antioxidant green tea -- for your health!" was an unauthorized nutrient content claim.[6] At the same time, FDA issued a warning letter to Redco Foods, Inc. regarding their Salada Naturally Decaffeinated Green Tea, stating that nutrient content claims using the term "antioxidant" must also comply with FDA regulations.[7] In August 2010, FDA issued a warning letter to Unilever, Inc. regarding antioxidant claims on that company's product "Lipton Green Tea", which stated that "Lipton Tea is made from tea leaves rich in naturally protective antioxidants.".[8] Similarly, on April 20, 2011, FDA issued a warning letter to Diaspora Tea & Herb Co. LLC regarding antioxidant

[5] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063064.htm
[6] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202823.htm
[7] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202832.htm
[8] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm

claims on White Tea, Yerba Maté Shade Grown, Organic Yerba Maté, Blueberry Rooibos, Organic Fair Trade Rooibos Blend, Green Rooibos (Green Bush), Organic Fair Trade Botanical, Matcha, 100% Premium Tea Powder, Genmai Green Tea, 100% Premium Tealeaf Powder, and Green Oolong Tea, 100% Premium Tealeaf Powder.[9] The Diaspora products contained a variety of antioxidant claims. In my opinion, the Twinings Company should be aware of, and heed the advice contained within, these FDA warning letters, as well as the requirements in FDA regulations.

14. In reaching my opinion, I relied on my education and experience at the FDA as well as the FDA labeling regulations, guidance and warning letters

I declare under oath that the foregoing is true and correct. This declaration was executed on March 4, 2015.

F. Edward Scarbrough

[9] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm252215.htm

Exhibit A

F. EDWARD SCARBROUGH 11 Tattershall Court, Germantown MD 20874
Telephone: (301) 916-9668 E-mail: Scarbrough.ed @gmail.com

EDUCATION

Ph.D. in Chemistry, Harvard University, 1971 (Doctoral thesis in Physical Chemistry under the direction of Nobel Laureate Professor William N. Lipscomb)
Masters of Arts, Chemistry, Harvard University 1966
B.S. in Chemistry, University of Tennessee, 1964

EMPLOYMENT HISTORY

Self-employed (2008 – present)

- **Scarbrough Consultants, LLC** – consulting on food regulatory policy, food safety and international harmonization.
  - Example: 2009 USDA contract to conduct food safety workshops in Ghana, Ethiopia, and Kenya
  - 2010 Cochran Fellowship Program two-week course on food labeling for food regulators from Thailand
  - Member, IFT Task Force on Global Policy and Regulations
  - Member, Food Industry Codex Coalition
- Volunteer work – example: member, Library Advisory Committee for Montgomery County Maryland

U.S. Department of Agriculture

- **U.S. Manager for Codex** (1997 – 2007) Coordinated all United States participation in activities of the Codex Alimentarius. This involved:
  - Serving as Codex Contact Point for the United States, which included distributing all documents received from Codex Alimentarius, creating and maintaining a US Codex web site, and creating and maintaining a reference library.
  - Appointing U.S. Delegates to Codex Committees and providing logistical support to U.S. Delegations.
  - Ensuring stakeholder participation in Codex activities by holding public meetings and circulating Codex documents and U.S. positions for comment.
  - Coordinating the development of, and often drafting, U.S. positions on Codex isssues, ensuring that all stakeholders and government agencies had an opportunity for input and ensuring consistency among U.S. positions to various Codex Committees.
  - Conducting training for U.S. Delegates in effective negoiation skills and cross-cultural interactions.
  - Conducting both domestic and international outreach efforts, which involved making presentations on Codex, the national and international organization of Codex activities and on controversial issuees in Codex.
  - Organizing and conducting international workshops on Codex, including several in Latin America, Asia, and Africa, as well as workshops for individual counntries such as India and China.

Food and Drug Administration

Director, Office of Food Labeling (1990 -1997) Responsible for planning, organizing, staffing, coordinating, and managing all regulatory programs, research projects, and other activities related to the labeling of food within the United States. This included:

- Directing the activities necessary to implement the Nutrition Labeling and Education Act of 1990, which required nutrition labeling on all processed foods sold in the U.S.; created the NUTRITION FACTS label.
- Managing the scientific research to develop analytical methodologies to enforce accurate nutrient values on food labels.

  - Directing consumer research on understanding and use of the food label, on dietary practices and on knowledge of the relationship of diet aand health.
  - Served as U.S. Delegate to the Cpdex Committee for Food Labelling
- **Director** (1988 - 1990)/ **Deputy Director** (1987 - 1988), **Office of Nutrition and Food Sciences** (Directed the Divisions of Nutrition, Microbiology, and Consumer Sciences)
  - Served as U.S. Delegate to the Codex Committee for Nutrition and Foods for Special Dietary Uses
- **Chief, Regulatory Affairs Staff, Office and Food Sciences** (1980 – 1987) (Developed regulations on sodium and cholesterol labeling, infant formula composition and good manufacturing practices, dietary supplements, nutrient bioavailability, food standards, etc)
- **Supervisory Chemist / Chemist, Division of Food and Color Additives** (1976 – 1980) Developed principles and procedures for the re-evaluation of the safety of substances added to foods, managed the review of industry submitted petitions for the approval of new food additives)

Academia

- **Chemistry Instructor, University of Pennsylvania** (1973-1977) (Taught chemistry to a wide variety of Penn students)
- **Researcher (Post-doctoral Fellow), University of Bern, Bern Switzerland** (1971 – 1973) (Established an organic crystallography section, including numerous computer programs)

AREAS OF EXPERTISE

Management

- Created, staffed and supervised the U.S. Codex Office, responsible for directing all U.S. participation in the Codex Alimentarius Commission, including coordinating governmental inter-agency and non-governmental stakeholders activities
- Spearheaded FDA's major food label reform initiative, by directing a multi-disciplinary team, resulting in nutrition labeling on virtually all processed packaged foods in the United States
- Directed FDA's regulatory programs for infant formula and dietary supplements, including labeling and good manufacturing practices
- Managed FDA's food-related surveillance and epidemiology programs, including post-market surveillance of adverse reactions to foods, human diet and health assessments, and surveys of consumer and marketplace behavior

Communication

- Delivered over 150 invited presentations, including major U.S. Codex and FDA policy statements in national and international meetings (Presentation list available on request)
- Served as U.S. Government spokesperson for Codex and FDA issues, in both electronic broadcast and print media
- Testified before Congress on several occasions
- Briefed Cabinet Secretaries and Ambassadors on major policy issues
- Developed regulations nutrition labeling, infant formula content and quality control, dietary supplements, nutrient bioavailability, food standards, etc.
- Served as government spokesperson on regulatory and international policies to professional associations, academic meetings, trade associations and consumer groups
- Taught a variety of chemistry courses

International Activities

- United States Delegate to:
  - Codex Alimentarius Commission
  - Executive Committee for the Codex Alimentarius Commission
  - Codex Committee on General Principles
  - Codex Committee on Food Labelling
  - Codex Committee on Nutrition and Foods for Special Dietary Uses
  - FAO/WHO Coordinating Committee for North America and the South-West Pacific

- Chairman of US/Canada Mexico NAFTA Technical Working Group on Food Labelling, Packaging and Standards
- Conducted U.S. Codex outreach activities in Latin American, the Caribbean, Africa, and Asia
- Member of U.S. Delegation to FAO/WHO International Conference on Nutrition (ICN)
- WHO consultant to the Ministry of Health, Malaysia, to help establish a food labeling program

Research and Reporting

- Major research projects in inorganic, organic and protein chemistry
- Published over 50 papers, covering subjects such as physical chemistry, crystallography, nutrition, food science, public health policy, international food standards and international trade (Publication list attached)
- Project Officer for several contracts with the National Academy of Sciences
- Principal investigator , NIH grant to crystallographically determine the structure of the enzyme, inorganic pyrophosphatase

Executive Liaison

- Member of USDA Biotechnology Policy Committee
- FDA representative to the Dietary Guidance Committee of the Nutrition Policy Board
- FDA liaison member of the Coordinating Committee for the National Cholesterol Education Program
- Member of FDA Task Force on Medical Foods and FDA Task Force on Health Messages on Food Labels

PROFESSIONAL RECOGNITION

- US Department of Agriculture Presidential Award
- Secretary of Health and Human Services' Superior Service Award
- Seven Food and Drug Administration Awards, including the Award of Merit, Commissioner's Special Citation, and Commendable Service Awards
- Member, American Chemical Society, American Institute of Nutrition and Institute of Food Technologists

ATTACHMENT

PUBLICATIONS RELATED TO FOOD LABELING

JOURNAL ARTICLES

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Lineback, D., J. DeVries, J. Slavin, A. Stephen, D. Gordon, L. Prosky, F.E. Scarborough, S. Lee, B. Olson and F. Clydesdale, 1995. Complex carbohydrates: the science and the label. Nutrition Reviews 53, 186-193.

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BOOK CHAPTERS

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TRADE PUBLICATIONS

Bender, M.M. and F.E. Scarbrough, 1995. Nutrition Labeling: FDA Policy on the Use of Databases. The World of Ingredients, January-February 1995: 54-56.

Scarbrough, F.E., 1992. Food labeling: The FDA Perspective. INFORM, International News on Fats, Oils and Related Materials, American Oil Chemists Society, Champaign IL, 3(8): 909-914.

PROCEEDINGS

Scarbrough, F.E., 1995. FDA Perspective on Labeling. Proceedings of Symposium on Complex Carbohydrate Definition, International Life Sciences Institute, Washington DC.

Scarbrough, F.E., 1995. Nutrition Labeling of Dietary Supplements and Health Claims: Developments in the USA and Implications for the Health Supplements Market. Proceedings of Nutrition'95 Summit, Singapore. Institute for International Research.

Scarbrough, F.E. 1992. FDA Regulations Regarding "Lite" Confections. Proceedings of the 46th Annual Production Conference, Pennsylvania Manufacturing Confectioners' Association, Medford NJ, pp 89-94.

ABSTRACTS

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Scarbrough, F.E., 2006. The Codex Alimentarius Commission and FDA. Abstracts, MARM 2006, American Chemical Society, Hershey, page 139.

Exhibit B

F. EDWARD SCARBROUGH 11 Tattershall Court, Germantown MD 20874
Telephone: (301) 916-9668 E-mail: Scarbrough.ed @gmail.com

DEPOSITIONS

December 16, 2013: Deposition in the case of Tricia Ogden, individually and on behalf of all others similarly situated, Plaintiff v. Bumble Bee Foods, LLC, Defandant

February 20, 2014: Deposition in the case of Natalia Bruton, individually and on behalf of all others similarly situated, Plaintiff, v. GERBER PRODUCTS COMPANY, et al., Defendants.

January 7, 2015 Deposition in the case of Brenda Center, individually and on behalf of others similarly situated, Plaintiff, v. OCEAN SPRAY CRANBERRIES, INC. Defendant.