UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.

STEPHANIE MILLER, an individual,
on behalf of herself and all others similarly
situated,

Plaintiff,

v.

LIVING HARVEST FOODS INC.,
an Oregon corporation,

Defendant.
_____/

CLASS ACTION COMPLAINT

Plaintiff Stephanie Miller ("Plaintiff") hereby sues for herself and all others similarly situated, Defendant Living Harvest Foods, Inc. ("Living Harvest" or "Defendant") and alleges as follows:

INTRODUCTION

1. Plaintiff brings this consumer class action on behalf of herself and all other persons who, from October 22, 2009 up to and including the present (the "Class Period"), purchased in Florida for consumption and not resale Living Harvest's Products[1] listing Evaporated Cane Juice ("ECJ") in the ingredients.

2. During the Class Period, Living Harvest engaged in a uniform campaign through which it purposefully misrepresented and continues to purposefully misrepresent to consumers that its Products contain ECJ even though "evaporated cane juice" is not "juice" at all—it is nothing more than sugar, cleverly disguised. Defendant conceals the fact that its Products have

[1] The term "Products" is defined as Living Harvest's Tempt Hempmilk – Original, Tempt Hempmilk – Vanilla, and Tempt Hempmilk – Chocolate.

added sugar by referring to the sugar as ECJ, a "healthy" sounding name made up by the sugar industry years ago to sell sugar to "healthy" food manufacturers for use in their consumer products. ECJ is not the common or usual name of any type of sweetener, or even any type of juice, and the use of such a name is false and misleading. Living Harvest uniformly lists ECJ as an ingredient on its Products, as well as on its website and other promotional material.

3. Living Harvest's actions constitute violations of Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201-501.2101. Living Harvest has also been unjustly enriched as a result of its conduct.

4. As a result of these unfair and deceptive practices, Living Harvest has collected millions of dollars from the sale of its Products with ECJ that it would not have otherwise earned.

PARTIES, JURISDICTION, AND VENUE

5. Plaintiff Stephanie Miller is a citizen of the State of Florida. During the Class Period, Plaintiff purchased Living Harvest Products with ECJ as an ingredient for personal consumption within the State of Florida. Plaintiff has purchased Living Harvest Products with ECJ, including the Tempt Hempmilk - Chocolate.

6. Defendant Living Harvest is a corporation organized and existing under the laws of the state of Oregon. Living Harvest's principal place of business is in Portland, Oregon. Living Harvest is a citizen of a state other than Florida. Living Harvest manufactured, advertised, marketed, and sold Products containing ECJ to tens of thousands of consumers nationwide, including Florida.

7. The Court has jurisdiction over Living Harvest because its Products with ECJ are advertised, marketed, distributed, and sold throughout Florida; Living Harvest engaged in the

wrongdoing alleged in this Complaint throughout the United States, including in Florida; Living Harvest is authorized to do business in Florida; and Living Harvest has sufficient minimum contacts with Florida and/or otherwise has intentionally availed itself of the markets in Florida, rendering the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice. Moreover, Living Harvest is engaged in substantial and not isolated activity within this state.

8. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, because this is a class action, as defined by 28 U.S.C. § 1332(d)(1)(B), in which a member of the putative class is a citizen of a different state than Defendant, and the amount in controversy exceeds the sum or value of $5,000,000, excluding interest and costs. *See* 28 U.S.C. § 1332(d)(2).

9. Venue is proper in this district because a substantial part of the events giving rise to Plaintiff's claims occurred in this district, and Living Harvest is subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

10. Living Harvest advertises and markets many of its Products as having ECJ, an unlawful term that is merely a false and misleading name for another less healthy food or ingredient that has a common or usual name, namely sugar. By using the term ECJ, Living Harvest is concealing the fact that it is adding sugar to its Products.

11. Living Harvest uses the term "Evaporated Cane Juice" on its packaging.

12. Living Harvest uses the term ECJ to make its Product appear healthier and to increase sales and to charge a premium.

13. Living Harvest's labeling of its Products identifies "Evaporated Cane Juice" as an ingredient, despite the fact that the FDA has specifically warned companies not to use the term

"Evaporated Cane Juice" because (1) it is "false and misleading;" (2) its use is in violation of a number of labeling regulations designed to ensure that manufacturers label their products with the common and usual names of the ingredients they use and accurately describe the ingredients they utilize; and (3) the ingredient in question is not a juice.

14. In October of 2009, the FDA issued Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, which advised industry that:

> [T]he term "evaporated cane juice" has started to appear as an ingredient on food labels, most commonly to declare the presence of sweeteners derived from sugar cane syrup. **However, FDA's current policy is that sweeteners derived from sugar cane syrup should not be declared as "evaporated cane juice" because that term falsely suggests that the sweeteners are juice…**
>
> "Juice" is defined by 21 CFR 120.1(a) as "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree." …
>
> As provided in 21 CFR 101.4(a)(1), "Ingredients required to be declared on the label or labeling of a food . . . shall be listed by common or usual name . . . ." The common or usual name for an ingredient is the name established by common usage or by regulation (21 CFR 102.5(d)). The common or usual name must accurately describe the basic nature of the food or its characterizing properties or ingredients, and may not be "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" (21 CFR 102.5(a))…
>
> Sugar cane products with common or usual names defined by regulation are sugar (21 CFR 101.4(b)(20)) and cane sirup (alternatively spelled "syrup") (21 CFR 168.130). Other sugar cane products have common or usual names established by common usage (e.g., molasses, raw sugar, brown sugar, turbinado sugar, muscovado sugar, and demerara sugar)…
>
> **The intent of this draft guidance is to advise the regulated industry of FDA's view that the term "evaporated cane juice" is not the common or usual name of any type of sweetener, including dried cane syrup. Because cane syrup has a standard of identity defined by regulation in 21 CFR 168.130, the common or usual name for the solid or dried form of cane syrup is "dried cane syrup."…**
>
> **Sweeteners derived from sugar cane syrup should not be listed in the ingredient declaration by names which suggest that the ingredients are juice, such as "evaporated cane juice." FDA considers such representations to be**

> **false and misleading under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because they fail to reveal the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups) as required by 21 CFR 102.5.** Furthermore, sweeteners derived from sugar cane syrup are not juice and should not be included in the percentage juice declaration on the labels of beverages that are represented to contain fruit or vegetable juice (see 21 CFR 101.30).

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm181491.html (emphasis added).

15. In 2012, the FDA followed up by sending two "warning letters" to the food industry telling them in no uncertain terms that their products are "misbranded" because their ingredient statements include "evaporated cane juice" which is "not the common or usual name of any type of sweetener." *See* Exhibit 1

16. Despite the issuance of the 2009 FDA Guidance and the 2012 warning letters, Living Harvest has not removed the unlawful and misleading reference to "evaporated cane juice" from its ingredient labels and continues to sell these misbranded Products to the consuming public.

17. Such Products mislead consumers into paying a premium price for products that do not satisfy the minimum standards established by law for those products and for inferior or undesirable ingredients or for products that contain ingredients not accurately listed on the label by its common name.

18. Living Harvest's false, unlawful, and misleading product descriptions and ingredient listings render these Products misbranded under Florida law. Specifically, Section 500.04 of the Florida Food Safety Act prohibits the manufacture, sale or delivery of "misbranded food." Food is "misbranded" when "its labeling is false or misleading in any particular" or when a food is "offered for sale under the name of another food." Fla. Stat. § 500.11(1)(a) & (b); Fla. Admin Code 5k-4.002. Misbranded products cannot be legally sold and are legally worthless.

19. Plaintiff and the class paid a premium price for their Living Harvest Products with ECJ.

20. Plaintiff and the Class have been damaged by Living Harvest's deceptive and unfair conduct in that they purchased a misbranded and worthless Product or paid prices they otherwise would not have paid had Living Harvest not misrepresented the Products' ingredients.

CLASS ACTION ALLEGATIONS

21. Plaintiff brings this case as a class action pursuant to Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§501.201-501.213. Plaintiff seeks certification of the following Class: All individuals who purchased any Living Harvest Product with ECJ for consumption and not resale in Florida after September 9, 2009 up to and including the present (the "Class"). Excluded from the Class are employees, officers, and directors of Living Harvest.

22. This action is proper for class treatment under Rules 23(b)(1)(B) and 23(b)(3) of the Federal Rules of Civil Procedure. While the exact number and identities of other Class members are unknown to Plaintiff at this time, Plaintiff is informed and believes that there are thousands of Class members. Thus, the Class is so numerous that individual joinder of all Class members is impracticable.

23. Questions of law and fact arise from Defendant's conduct described herein. Such questions are common to all Class members and predominate over any questions affecting only individual Class members and include:

a. whether listing sugar as ECJ on its Products is false and misleading;

b. whether listing the ingredient "evaporated cane juice" is misleading because it is not "juice;"

c. whether identifying sugar as ECJ renders the Products at issue misbranded;

d. whether Living Harvest failed to disclose to consumers that ECJ is an unlawful term that is merely sugar;

e. whether Living Harvest engaged in a marketing practice intended to deceive consumers by substituting the term ECJ for sugar in its Products;

f. whether Living Harvest's marketing practices violate FDUTPA;

g. whether Living Harvest has been unjustly enriched at the expense of Plaintiff and the other Class members by its misconduct;

h. whether Living Harvest must disgorge any and all profits it has made as a result of its misconduct; and

i. whether Living Harvest should be barred from marketing its Products as listing ECJ as an ingredient.

24. Plaintiff will fairly and adequately represent and pursue the interests of the Class. Plaintiff's counsel has vast experience in litigating consumer class action cases. Plaintiff understands the nature of her claims herein, has no disqualifying conditions, and will vigorously represent the interests of the Class.

COUNT I- INJUNCTION FOR VIOLATIONS OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT

25. Plaintiff realleges and incorporates by reference paragraphs 1 - 24 herein and further alleges as follows:

26. This is a claim for an injunction for violations of Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201-501.2101.

27. FDUTPA provides that unfair methods of competition, unconscionable acts and practices, and unfair or deceptive acts or practices in the conduct "of any trade or commerce" are unlawful. Fla. Stat. §501.204. Under FDUTPA, "trade or commerce" is defined to include any advertisement or solicitation relating to any "thing of value." Fla. Stat. §501.203(8).

28. Plaintiff and the other Class members are consumers as defined and construed under FDUTPA, Fla. Stat. §§501.201-501.213. Further, Plaintiff and the other Class members are "aggrieved" by the sale of Products listing ECJ as an ingredient in that they purchased said Products.

29. The practices employed by Defendant, whereby Defendant sells its Products with the ingredient ECJ is unfair, deceptive, and misleading. In addition, the practice employed by Defendant, whereby Defendant sells Products that contain ECJ constitutes a *per se* violation of FDUTPA under Section 501.203(3)(c) because it is in violation of the Florida Food Safety Act, Fla. Stat. § 500.04 (1) and (2) in that said Products are misbranded. These practices would likely deceive a reasonable consumer.

30. Living Harvest should be enjoined from marketing its Products as containing ECJ as described above pursuant to Fla. Stat. § 501.211(1).

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, respectfully demands a judgment enjoining Living Harvest's conduct, awarding costs of this proceeding and attorney's fees, as provided by Fla. Stat. § 501.2105, and such other relief as this Court deems just and proper.

COUNT II- VIOLATIONS OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT

31. Plaintiff realleges and incorporates by reference paragraphs 1 - 24 herein and further alleges as follows:

32. This is a claim for violation of Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201-501.2101.

33. FDUTPA provides that unfair methods of competition, unconscionable acts and practices, and unfair or deceptive acts or practices in the conduct "of any trade or commerce" are

unlawful. Fla. Stat. §501.204. Under FDUTPA, "trade or commerce" is defined to include any advertisement or solicitation relating to any "thing of value." Fla. Stat. §501.203(8).

34. Plaintiff and the other Class members are consumers as defined and construed under FDUTPA, Fla. Stat. §§501.201-501.213.

35. The practices employed by Defendant, whereby Defendant sells its Products with the ingredient ECJ are unfair, deceptive, and misleading. In addition, the practice employed by Defendant, whereby Defendant sold, promoted and marketed that its Products that contain ECJ constitutes a *per se* violation of FDUTPA under Section 501.203(3)(c) because it is in violation of the Florida Food Safety Act, Fla. Stat. § 500.04 (1) and (2) in that said Products are misbranded. These practices would likely deceive a reasonable consumer.

36. Plaintiff and the other Class members suffered a loss as a result of Living Harvest's deceptive and unfair trade acts. Specifically, as a result of Living Harvest's deceptive and unfair trade acts and practices, Plaintiff and the other Class members suffered monetary losses associated with the purchase of Living Harvest Products with ECJ, *i.e.*, the purchase price of the Product and/or the premium paid by Plaintiff and the Class for said Products.

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, respectfully demands an award against Living Harvest for actual and/or compensatory damages, in addition to the costs of this proceeding and attorney's fees, as provided by Fla. Stat. § 501.2105, and such other relief as this Court deems just and proper.

COUNT III- UNJUST ENRICHMENT

37. Plaintiff realleges and incorporates the allegations contained in paragraphs 1 - 24 herein and further alleges as follows:

38. Living Harvest received certain monies as a result of its uniform deceptive marketing of its Products with ECJ that are excessive and unreasonable.

39. Plaintiff and the Class conferred a benefit on Living Harvest through purchasing its Products with ECJ, and Living Harvest has knowledge of this benefit and has voluntarily accepted and retained the benefits conferred on it. It would be inequitable for Living Harvest to retain this benefit.

40. Each Class member is entitled to an amount equal to the amount they enriched Living Harvest and for which Living Harvest has been unjustly enriched.

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, demands an award against Living Harvest for the amounts equal to the amount each Class member enriched Living Harvest and for which Living Harvest has been unjustly enriched, and such other relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

41. Plaintiff, individually and on behalf of all others similarly situated, hereby demands a jury trial on all claims so triable.

Dated: October 29, 2013

Respectfully submitted,

s/ Lance A. Harke
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JS 44 (Rev. 12/12)

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 NEXT PAGE OF THIS FORM.)* **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS

STEPHANIE MILLER, an individual, on behalf of herself and all others similarly situated,

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Harke Clasby & Bushman, LLP, 9699 NE Second Avenue, Miami Shores, FL 33138, Telephone: 305-536-8220, Facsimile: 305-536-8229

DEFENDANTS

LIVING HARVEST FOODS INC., an Oregon corporation,

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

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

Attorneys *(If Known)*

(d) Check County Where Action Arose: ☑ MIAMI-DADE ☐ MONROE ☐ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

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
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical 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
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence

Other:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee – Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 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
- ☐ 375 False Claims Act
- ☐ 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
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed (See VI below) ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment ☐ 8 Remanded from Appellate Court

VI. RELATED/ RE-FILED CASE(S)

(See instructions): a) Re-filed Case ☐YES ☑NO b) Related Cases ☐YES ☑NO

JUDGE DOCKET NUMBER

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. § 1332. Action to recover damages sustained as a result of Defendant's listing of Evaporated Can Juice

LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. 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

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

DATE: October 29, 2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ IFP _____ JUDGE _____ MAG JUDGE _____

United States District Court

SOUTHERN DISTRICT OF FLORIDA

STEPHANIE MILLER, an individual, on behalf of herself and all others similarly situated,

Plaintiff,

v.

LIVING HARVEST FOODS INC., an Oregon corporation,

Defendant.
_____/

SUMMONS IN A CIVIL CASE

CASE NO.:

TO: Living Harvest Foods, Inc.
Catherine Hearn, Registered Agent
12770 SW Blue Heron Place
Tigard, OR 97223

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Harke Clasby & Bushman LLP
9699 NE Second Avenue
Miami Shores, FL 33138
Telephone: 305-536-8220
Facsimile: 305-536-8229

an answer to the complaint which is herewith served upon you, within twenty one (21) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the Complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

_____ _____

CLERK **DATE**

_____

BY DEPUTY CLERK

EXHIBIT 1

Inspections, Compliance, Enforcement, and Criminal Investigations

Hail Merry, LLC 10/23/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

October 23, 2012

2013-DAL-WL-006

WARNING LETTER

UPS OVERNIGHT

Sarah P. Chapin, Chief Executive Officer
Susan O'Brien, Owner
Hail Merry, LLC
8805 Sovereign Row, Suite 101
Dallas, TX 75247

Dear Ms. Chapin and Ms. O'Brien:

The U.S. Food and Drug Administration (FDA) inspected your food manufacturing facility located at 8805 Sovereign Row, Suite 101, Dallas, Texas from October 17 through 19, 2011. During this inspection we collected labels for your food products Grawnola Orange Cranberry (1.75 oz), Merry's Miracle Tart Chocolate (3 oz), Almonds Vanilla Maple (1.75 oz), and Sunflower Seeds Salt n Black Pepper (4 oz). We also reviewed your website at www.hailmerry.com. Based on our review of your labels and your website, w have concluded that your products are in violation of sections 403, 505(a), and 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §§ 343, 355(a), and 352(f)(1)] and the regulations implementing the food labeling requirements of the Act, which are found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links in FDA's website at www.fda.gov[1] .

Unapproved New Drugs

Your labeling, including your product labels and your website, www.hailmerrv.com, promotes your food products for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your labeling establish that your products are drugs because they ar 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 found on your website include:

From the brochure located on your webpage entitled "Why"

- "Raw nuts and cold pressed coconut oil [ingredients in many of your products such as Merry's Miracle Tart Chocolate, Almonds Vanilla Maple,
and Grawnola Orange Cranberry] ... improve our cholesterol profile . . . [and] reduce inflammation . .. "
- "Coconut oil [an ingredient in many of your products such as Merry's Miracle Tart Chocolate] helps to reduce bad cholesterol!"
- "Coconut oil contains large amounts of Lauric Acid which is anti-viral . ... "

From the webpage entitled "Category Archives: Diabetes" which can be accessed from your website by clicking on the link "Biog" and then clicking on the link "Diabetes"

• "Coconut Oil Can Reduce the Symptoms of Type 2 Diabetes"
• "Diabetics can use coconut oil to help regulate blood glucose levels . ... Luckily, Hail Merry offers a variety of raw, vegan and gluten-free snacks that contain coconut oil."

From the webpage entitled "Category Archives: Celiac Disease" which can be accessed from your website by clicking on the link "Slog" and then clicking on the link "Celiac Disease"

• "[W]hile going gluten-free [all of your products are labeled as gluten-free] is costly ... the benefits are enormous including finding relief from the symptoms of multiple sclerosis, rheumatoid arthritis, chronic fatigue, migraines, irritable bowel syndrome and even infertility ... . "
• "Jenny McCarthy went gluten-free along with her son Evan and even says that the diet has played an essential part in Evan's recovery from autism . .

. . Join the movement and check out Hail Merry gluten-free snacks."

Further, your Almonds Vanilla Maple product label also contains the following claim:

"Research suggests that eating about a handful of almonds each day can help lower cholesterol levels"

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the 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 U.S. without prior approval from 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.

Furthermore, because your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions for use cannot be written so that a layperson can use the drug safely for its intended uses. Thus, the labeling fails to bear adequate directions for use, causing the products to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction of misbranded drugs into interstate commerce is a violation of § 301 (a) of the Act [21 U.S.C. § 331 (a)].

Misbranding Violations

Even if your Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper products did not contain claims on your labeling that cause them to be unapproved new and misbranded drugs, they would still be misbranded foods under section 403 of the Act (21 U.S.C. § 343) in that the labels for these products do not comply with the food label requirements in 21 CFR Part 101 as follows:

1. Your Merry's Miracle Tart Chocolate product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the label bears a false and misleading claim "good fats." This claim is false and misleading because of the high levels of saturated fat in the products. As discussed below, the correct serving size for your product should be one tart. One tart is 85g, and contains approximately 12g of saturated fat, which is 60% of the DV for saturated fat.

The relationship between saturated fat intake and risk of coronary heart disease is well established (DHHS and USDA, Dietary Guidelines for Americans, 2005, 6th Edition, Washington, D.C., U.S. Government Printing Office, January 2005). Because of the high level of saturated fat in your Merry's Miracle Tart Chocolate product, the claim "good fats" is false and misleading.

2. Your Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper 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 labels bear nutrient content claims, but the products do not meet the requirements to bear the claims. Under section 403(r)(1)(A) 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 authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling without complying with the specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act. For example:

• Your Grawnola Orange Cranberry, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper product labels contain the nutrient content claim, "RICH IN OMEGAS". Although various nutrient content claims for ALA, DHA, and EPA omega-3 fatty acids have been statutorily authorized through the notification procedure in section 403(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)], the claims for Omegas on your labels do not meet the requirements for any of these claims. Specifically, among other requirements, the claims authorized under the

notification procedure must specify whether the claim is referring to ALA, DHA, or EPA omega-3 fatty acids.[1]

• Your Merry's Miracle Tart Chocolate product label bears the nutrient content claim "Coconut oil is cholesterol free." However, your product does not meet the requirements in 21 CFR 101.62(d)(1) to bear this claim because your products do not contain 2 g or less of saturated fatty acids per reference amount customarily consumed (RACC) and per labeled serving. According to your nutrition information, a 28 g serving of Merry's Miracle Tart Chocolate contains 4 g of saturated fat.

• Your Grawnola Orange Cranberry product label bears the nutrient content claim "Cranberries are loaded with antioxidants." Nutrient content claims using the term "antioxidant" must compl 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 20 percen 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 claim found on your product labels is a nutrient content claim because it characterizes the level of antioxidants in your products, but it does not comply with 21 CFR 101.54(g)(4) because the claim does 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.

• Your Sunflower Seeds Salt n Black pepper product label contains the nutrient content claim "[R]ich source [of] ... iron ." A product that claims to be "rich" in a nutrient must contain at least 20 percent of the RDI per RACC for the nutrient as required by 21 CFR 101 .54(b). Based upon your nutrition information, a 28 g serving contains 10 percent of the RDI for iron. This equates to approximately 11% of RDI per RACC. Therefore, your product does not meet the requirements to bear a "rich" claim for iron. In addition, your Sunflower Seeds Salt n Black pepper product label contains the nutrient content claim "[R]ich source [of] . . . B vitamins, vitamin E as well as minerals copper, manganese, potassium, and magnesium, however the nutrient levels are not declared for these vitamins and minerals as required under 21 CFR 101.9(c)(8)(ii) and 101.13(n). Therefore the product is misbranded under section 403(q) and 403(r)(1)(A) of the Act. Further, because these nutrient levels are not declared, it is not clear whether the product has the required minimum 20 percent of the RDI per RACC of these nutrients as required under 21 CFR 101.54(b).

• Your website also bears the implied nutrient content claim, "healthy" for your Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper products. Examples of these claims include:

From the webpage entitled "Category Archives: Diabetes" which can be accessed from your website by clicking on the link "Biog" and then clicking on the link "Diabetes"

> "Hail Merry Snacks are perfect healthy snacks for diabetics .... "

From the webpage entitled "Rawk the Party 20 pack-Chocolate Miracles Tarts in reference to the Merry's Miracle Tart Chocolate product

> "The perfect indulgence (but one that's healthy!) ... . "

From the webpage entitled "Break Room Snacks Assortment" which includes the Grawnola Orange Cranberry, Almonds Vanilla Maple and
Sunflower Seeds Salt n Black Pepper products

> "There's no reason your office breakroom or pantry shouldn't have ... . healthy snacks on hand . ... "

However, these products do not meet the requirements for use of the term "healthy" as set forth in 21 CFR 101.65(d)(2). To bear an implied nutrient content claim using the term "healthy," foods must meet the following requirements:

(1) Must be "low fat" as defined in 21 CFR 101.62(b)(2) (total fat content of 3 g or less per RACC);
(2) Must be "low saturated fat" as defined in 21 CFR 101.62(c)(2) (saturated fat content of 1 g or less per RACC and no more than 15 percent of calories from saturated fat);
(3) Must not exceed the disclosure level for cholesterol set forth in 21 CFR 101.13(h) (60 mg cholesterol per RACC);
(4) Must contain at least 10% of the Daily Value per RACC of one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, or fiber; and
(5) Must contain no more than 480 mg sodium per RACC and per labeled serving.

Your products Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black
Pepper do not meet the definition of low fat. In addition, your Merry's Miracle Tart Chocolate does no meet the definition of low in saturated fat.

• Your Sunflower Seeds Salt n Black Pepper product label bears the claim "rich source [of] linoleic acid" and your brochure on your webpage entitled "Enlighten" under the heading "Hail Merry is a Certified Gluten-free Kitchen" bears the claim "Buckwheat groats [ingredient in Grawnola Orange Cranberry] are . . . loaded with amino acids." These claims characterize the levels of nutrients of the type required to be in nutrition labeling in your products by use of the terms "rich source" and "loaded with ." Even if we determined that the term "loaded with" could be considered synonymous with a term defined by regulation (e.g., "good source" or "high"), these claims do not comply with the requirements in 21 CFR 101.54(b) because there is no established RDI or DRV for linoleic acid or amino acids.

3. Your Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate, Almonds Vanilla Maple and Sunflower Seeds Salt n Black Pepper products are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the nutrition information is not declared in accordance with 21 CFR 101.9. Specifically,

• Your Sunflower Seeds Salt n Black pepper product label contains the nutrient content claim "[R]ich source [of] ... B vitamins, vitamin E as well as minerals copper, manganese, potassium, magnesium, and iron ." As required by 21 CFR 101.9(c)(8)(ii), the declaration of vitamins and minerals as a percent of the RDI shall include vitamins A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) when they are added as a nutrient supplement, or when a claim is made about them. Also, as required by 21 CFR 101.9(c)(5), the declaration of the amount of potassium is required when a claim is made about potassium content. Your label fails to declare the percentage of B vitamins vitamin E, copper, manganese, and magnesium and the amount of potassium.

• The serving size declared on your Merry's Miracle Tart Chocolate does not meet the requirements in 21 CFR 101.9(b)(2)(i). The serving size for products in discrete units shall be one unit if a unit weighs 67 percent or more, but less than 200 percent, of the reference amount. The RACC for Bakery Products, Pies, cobblers, fruit crisps, turnovers, other pastries is 125g (21 CFR 101.12(b), Table 2). Your label incorrectly declares the serving size as "(1/3 tart (28g)." One tart weighs 85g which is 80% of the RACC; therefore your serving size should be one tart. The nutrition values and servings per container information provided on the label of your product must be based on the correct serving size.

• Your Grawnola Orange Cranberry, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper products fail to list the serving size in common household measure in accordance with 21 CFR 101.9(b)(5), such as in cups, tablespoons, teaspoons, or, if appropriate, the number of pieces.

4. Your Grawnola Orange Cranberry product is misbranded within the meaning of Section 403(i)(2) o the Act [21 U.S.C. § 343(i)(2)], because it is fabricated from two or more ingredients, but the label fails to declare the common or usual name of each ingredient in the product in accordance with 21 CFR 101.4. Specifically, your product lists, "Evaporated Cane Juice" in the ingredient statement; however, evaporated cane juice is not the common or usual name of any type of sweetener. The proper way to declare this ingredient can be found on the FDA website at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm181491.htm[2].

The above list is not intended to be an all-inclusive list of violations in your products, labels, and labeling. I is your responsibility to assure that the products you market are in compliance with all requirements of the

Act and federal regulations. You should take prompt measures to correct all violations described in this letter and prevent their recurrence. Failure to take appropriate corrective action may subject your firm and products to further actions, such as injunction or seizure.

We also note that your webpage entitled "Category Archives: Diabetes" which can be accessed from your website by clicking on the link "Slog" and then clicking on the link "Diabetes" bears the statement "Hail Merry Snacks are perfect healthy snacks for diabetics .. . . ". Prior to June 1996, there was a special dietary regulation (21 CFR 105.67) that provided for the special dietary claim "may be useful in the diet of diabetics" on food product labels. In the Federal Register (FR) of June 3, 1996 (61 FR 27771), FDA revoked 21 CFR 105.67. FDA concluded, consistent with current dietary advice, that the provisions for diabetic labeling in 21 CFR 105.67 were outdated and misleading. The agency also stated in that Federal Register notice that the nutrient content and health claim provisions of the Act and section 403(a) would prevent any use of the term "diabetic" that is not scientifically valid or that is misleading. Therefore, we recommend you remove the language from the labeling of your snack products.

We also note that your Grawnola Orange Cranberry, Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper products bear the claim "NO REFINED SUGAR." However, the intent of your claim may not be clear to consumers and may mislead those who are seeking products that are sugar-free or contain no added sugar. We recommend that you clarify the meaning of your claim.

You should notify this office in writing within fifteen (15) working days from your receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent their recurrence. In your response, include documentation of your corrective actions. If you cannot complete all corrective actions before you respond, you should explain the reason for your delay and state when you will correct the remaining violations.

Your written response should be sent to Seri L. Essary, Compliance Officer, U.S. Food and Drug Administration, 4040 North Central Expressway, Dallas, TX, 75204. If you have questions regarding any issues in this letter, please contact Ms. Essary at (214)253-5335.

Sincerely,

/s/

Reynaldo R. Rodriguez, Jr.
Dallas District Director

[1] FDA issued a proposed rule (72 FR 66103, November 27, 2007) to prohibit some of these nutrient content claims for omega-3 fatty acids.

Page Last Updated: 11/02/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Silver Spring, MD 20993
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Email FDA

Links on this page:

1. http://www.fda.gov
2. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm181491.htm

Inspections, Compliance, Enforcement, and Criminal Investigations

Bob's Red Mill Natural Foods, Inc. 7/31/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Ave SE, Suite 210
Bothell, WA 98021
Telephone: 425-302-0340
FAX: 425-302-0402

July 31, 2012

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply, refer to Warning Letter SEA 12-28

Robert G. Moore, President and CEO
Bob's Red Mill Natural Foods, Inc.
13521 SE Pheasant Court
Milwaukie, Oregon 97222

WARNING LETTER

On December 13-14, 2011, the U.S. Food and Drug Administration (FDA) conducted an inspection of your firm located at 13521 SE Pheasant Court, Milwaukie, Oregon. Our inspection found significant violations of the food labeling regulations, Title 21, Code of Federal Regulations (21 CFR Part 101). During this inspection, the FDA collected a sample of your Whole Grain Low-Carb Bread Mix. An analysis of the collected sample and a review of your product labeling demonstrate that your Whole Grain Low-Carb Bread Mix product is misbranded within the meaning of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343]. You may find the Act and the referenced CFR regulations through links on FDA's internet home page at www.fda.gov[1].

FDA analyzed your Whole Grain Low-Carb Bread Mix product to determine whether the information in the Nutrition Facts panel accurately reflects the nutrient content of the product. Your label states that the product contains 11 grams of protein per serving size of 21 grams. However, FDA's analysis, which was based on the Kjeldahl nitrogen method, found that your product contained 8.15 grams of protein per serving, which is 74.1 percent of the amount declared on the label. A check analysis found 7.67 grams of protein per serving, which is 69.7 percent of the amount declared on the label. Therefore, your product is misbranded under Section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading because the amount of protein content is less than 80 percent of the amount declared [21 CFR 101.9(g)(4)(ii)].

Your Whole Grain Low-Carb Bread Mix is misbranded within the meaning of Section 403(q) of the Act [21 U.S.C. § 343(q)], in that the nutrition facts information is not in an appropriate format in accordance with 21 CFR 101.9. For example:

- Your product declares the serving size as "1 Slice (21 g dry mix)." The Reference Amount Customarily Consumed (RACC) for bread is 50 grams; therefore, the serving size of a bread mix must be the

amount of mix that is required to make the reference amount of 50 grams [21 CFR 101.12(c)(2)] and it must be declared in a household measure that is appropriate for a powdered mix.

- The sodium content is not rounded in accordance with 21 CFR 101.9(c)(4).
- The percent daily value for iron is not rounded in accordance with 21 CFR 101.9(c)(8)(iii).

Your Whole Grain Low-Carb Bread Mix is misbranded within the meaning of Section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)], because it is fabricated from two or more ingredients, but the label fails to declare the common or usual name of each ingredient in the product in accordance with 21 CFR 101.4. Specifically, your product lists, “Evaporated Cane Juice” in the ingredient statement; however, evaporated cane juice is not the common or usual name of any type of sweetener. The proper way to declare this ingredient can be found at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm181491.htm[2].

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

During our label review we also noted these additional observations:

- You declare the amount of “Net Carbs” on your product label; however, the label does not adequately describe how the number of “net carbs” is derived. It appears that the “net carbs” number was calculated by subtracting the number of grams of dietary fiber from the number of grams of total carbohydrate but there was no explanation on the label. The statement and explanation must be truthful and not misleading.
- In accordance with 21 CFR 101.9(c)(6), the amount of total carbohydrate is calculated by subtraction of the sum of crude protein, total fat, moisture and ash from the total weight of the food. Therefore, if the amount of protein is less than the amount declared on the label, as indicated above, the total carbohydrate amount may be greater than the amount declared on the label.
- The information panel includes intervening material between the nutrition label and the manufacturer name and address [21 CFR 101.2(e)].

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Jessica L. Kocian, Compliance Officer, U.S. Food and Drug Administration, 22215 26th Ave SE, Suite 210, Bothell, Washington 98021. If you have any questions about this letter, please contact Compliance Officer Jessica Kocian at 425-302-0444.

Sincerely,
/S/
Charles M. Breen
District Director

cc: Dennis R. Vaughn, Vice President of Operations
13521 SE Pheasant Court
Milwaukie, Oregon 97222

Oregon Department of Agriculture
Food Safety Division
635 Capitol Street NE
Salem, Oregon 97301

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