

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,	)
	)
Plaintiff,	)
	)
v.	)
	)
BROWNWOOD ACRES FOODS, INC., and	)
CHERRY CAPITAL SERVICES, INC.	)
d.b.a. FLAVONOID SCIENCES,	)
corporations, and STEPHEN C.	)
de TAR and ROBERT L. UNDERWOOD,	)
individuals,	)
	)
Defendants.	)

CIVIL NO.

**1:08-cv-148**

HON.

**Paul L Maloney  
US District Judge**

**COMPLAINT FOR  
PERMANENT INJUNCTION**

INTRODUCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Brownwood Acres Foods, Inc. and Cherry Capital Services, Inc., d.b.a. Flavonoid Sciences, corporations, and Stephen C. de Tar and Robert L. Underwood, individuals (hereafter collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

c. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(r)(1)(B).

#### JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

#### DEFENDANTS

4. Defendant Brownwood Acres Foods, Inc. ("Brownwood Acres") is incorporated under the laws of the State of Delaware, with its principal place of business located at 4819 US Highway 31, Eastport, Michigan, within the jurisdiction of this Court. Brownwood Acres is engaged in the manufacture and/or distribution of various products including, but not limited to, juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules.

5. Defendant Cherry Capital Services, Inc. ("Cherry Capital") is incorporated under the laws of the State of Michigan, with its principal place of business at 2811 Cass Road, Suite C-1, Traverse City, Michigan, within the jurisdiction of this Court. Cherry Capital has been doing business as Flavonoid Sciences since 2002. Cherry Capital manufactures fruit paste, contracts with other companies for the manufacture of finished products (fruit bars and soft fruit gel capsules), and then has the finished

products shipped to Brownwood Acres for sale and distribution. Virtually all of Cherry Capital's fruit products are marketed and distributed by Brownwood Acres.

6. Defendant Stephen C. de Tar, an individual, is the President and owner of Brownwood Acres and Vice President and part owner (50%) of Cherry Capital. He is the most responsible individual for the day-to-day operations of Brownwood Acres. He is responsible for, and has authority over, the marketing of Brownwood Acres' and Cherry Capital's products, including the claims made through the following websites owned and controlled by Brownwood Acres: brownwoodacres.com; flavonoidsciences.com; fruitfast.com; blueberrypower.com. Defendant de Tar is also responsible for and has the ability to edit the content of the Fruit Institute website (fruitinstitute.org). Defendant de Tar resides and conducts business in Michigan, within the jurisdiction of this Court.

7. Defendant Robert L. Underwood, an individual, is the President and part owner of Cherry Capital. He is the most responsible individual for the day-to-day operations of the company. Defendant Robert Underwood resides and conducts business in Michigan, within the jurisdiction of this Court.

#### LEGAL STANDARDS

8. Under the Act, any product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

9. The intended use of a product may be determined from any relevant source. See 21 C.F.R. § 201.128.

10. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment is not necessary; rather, the Court has held that an article "accompanies" another when one supplements or explains the other such as a committee report of the Congress "accompanies" a bill.

11. Under the Act, a new drug is any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1).

12. Under the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or an abbreviated new drug application with respect to the drug, or it qualifies for an exemption as an investigational new drug. 21 U.S.C. § 355.

13. The introduction or delivery for introduction into interstate commerce of an unapproved new drug is a violation of the Act, 21 U.S.C. § 331(d).

14. A drug is misbranded if its label fails to bear "adequate directions for use" as defined by 21 C.F.R. § 201.5(a), and it does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1).

15. The introduction or delivery for introduction into interstate commerce of a drug that is misbranded is a violation of the Act, 21 U.S.C. § 331(a).

16. A "health claim" is a claim that food manufacturers put on conventional foods and dietary supplements that describe a relationship between the food and reducing a risk of a disease or health-related condition. Under the Act, FDA may authorize a health claim to be used on conventional foods only if the agency "determines, based on the totality of the publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 U.S.C. § 343(r)(3)(B)(i).

17. A food is deemed misbranded under the Act if it contains an unauthorized health claim. 21 U.S.C. § 343(r)(1)(B).

18. The introduction or delivery for introduction into interstate commerce of misbranded foods is a violation of the Act, 21 U.S.C. § 331(a).

#### DEFENDANTS' CLAIMS FOR THEIR PRODUCTS

19. Defendants own and control various websites from which customers can purchase their products: brownwoodacres.com; flavonoidsciences.com; fruitfast.com; and blueberrypower.com. Defendants are also responsible for and control the content of the Fruit Institute website, fruitinstitute.org. Prior to November 2007, when Plaintiff informed Defendants of its intention to file suit in this matter, these websites, at various times, included numerous claims that certain fruits can cure, treat, mitigate, prevent, and/or reduce the risk of various diseases including, but not limited to, cancer, diabetes, arthritis, gout, Alzheimer's disease, and heart disease.

20. FDA investigators confirmed as part of a June 2004 inspection of Brownwood Acres (including its website, www.brownwoodacres.com) and January 2005

review of Cherry Capital's website, [www.flavonoidsciences.com](http://www.flavonoidsciences.com), that these websites contained numerous claims that Defendants' products could cure, mitigate, treat, or prevent various diseases including, but not limited to, cancer, arthritis, gout, urinary tract infections, heart disease, and Alzheimer's disease.

21. Four days after being notified by FDA that the claims made for Defendants' products on the Brownwood Acres and Flavonoid Sciences websites caused their products to be unapproved new drugs in violation of the Act, Defendant de Tar asked the same individual who designed the Brownwood Acres and Flavonoid Sciences websites to design a new website titled "The Fruit Institute," [www.fruitinstitute.org](http://www.fruitinstitute.org). Defendants moved the claims that caused their products to be unapproved new drugs in violation of the Act from the Brownwood Acres and Flavonoid Sciences website to the new "Fruit Institute" website. The Brownwood Acres and Flavonoid websites included hyperlinks (or "hot links") to the Fruit Institute website, and the Fruit Institute website included hyperlinks back to the Brownwood Acres and Flavonoid websites. Using these "hot links," a customer could review a claim made for a product on the Fruit Institute website and then click the link to view the Brownwood Acres and/or Flavonoid websites, where the product could be purchased. A customer also could purchase a fruit product on the Brownwood Acres and/or Flavonoid websites and then click the link to view the Fruit Institute website claims regarding the health benefits of the product. Brownwood Acres and Flavonoid Sciences were occasionally listed as sponsors on the Fruit Institute website.

22. On September 18, 2006, FDA confirmed that Defendants modified the Flavonoid Sciences website, changing the hot link to the Fruit Institute website to a "cold

link.” Similarly, on December 12, 2006, FDA confirmed that Defendants modified the Brownwood Acres website, changing the hot link to the Fruit Institute website to a cold link. This meant that a customer could purchase a product on the Brownwood Acres and/or Flavonoid websites and then, as directed by Defendants' instructions, either re-type or cut and paste the Fruit Institute web address into the browser to review claims regarding the health benefits of the product.

23. With respect to the hot link on the Fruit Institute website to the Brownwood Acres and Flavonoid Sciences websites, FDA confirmed that these hot links remained active until January 2007. On January 12, 2007, FDA confirmed that these hot links had been changed to cold links. Later that month, on January 29, 2007, FDA confirmed that the cold links to the Brownwood Acres and Flavonoid Sciences websites had been removed, and that there were no longer any references to these websites on the Fruit Institute website.

24. Prior to November 2007, when Plaintiff informed Defendants of its intention to file this suit, the Brownwood Acres and Flavonoid websites, as well as Defendants' other two websites (fruitfast.com and blueberrypower.com), contained the following (or similar) cold link referring customers to the Fruit Institute website:

Studies continue to show the many health benefits that daily consumption of fruits can provide. Because the products we sell are so effective and are natural products - not drugs, the FDA will not allow us to publish studies, even those performed by the USDA, with disease claims related to various fruits. We recommend the following website with research related to fruit consumption: [www.fruitinstitute.org](http://www.fruitinstitute.org). Please copy and paste the url above into your browser. We cannot link directly to this site, again due to FDA regulations. We believe you will find the information quite enlightening.

(emphasis added). The "Testimonials" page on the Brownwood Acres website had similar language referring customers to claims regarding "our products" on the Fruit Institute website.

25. Since at least 2005, Brownwood Acres has also sold on its website liquid glucosamine under the name "Syn-flex 1500." Prior to Plaintiff contacting Defendants regarding this suit, the Brownwood Acres website contained numerous claims that "Syn-flex 1500" can cure, mitigate, treat, or prevent arthritis. These claims, which are among those set forth in detail in paragraph 36 below, cause these products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

26. Since at least 2005, Brownwood Acres has sold on its website salmon oil capsules under the name "Alaskan Sockeye Salmon Oil Capsules." Prior to Plaintiff contacting Defendants regarding this suit, the Brownwood Acres website included a hot link to another website that Defendants stated "offers a wealth of information on omega-3 fatty acids and their numerous health benefits." This other website, the International Cod Liver Omega 3 Foundation ([www.clo3.com](http://www.clo3.com)), includes numerous claims that omega-3 fatty acids may protect against or reduce the risk of diseases including, but not limited to, heart disease, breast and prostate cancer, stroke, attention-deficit disorder, and Alzheimer's disease. These claims, which are set forth in detail in paragraph 36 below, cause these products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

27. Prior to Plaintiff contacting Defendants regarding this suit, the Fruit Institute website included numerous claims that various fruits can cure, treat, mitigate, or prevent various diseases including, but not limited to, cancer, diabetes, arthritis, gout,



Alzheimer's disease, and heart disease. These claims, which are set forth in detail in paragraph 36 below, cause Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

28. Prior to Plaintiff contacting Defendants regarding this suit, the Fruit Institute website also included numerous claims that various fruits can reduce the risk of various diseases including, but not limited to, cancer, heart disease, and Alzheimer's disease. These claims, which are set forth in detail in paragraph 36 below, constitute health claims. Because none of these claims are authorized by the FDA, nor has FDA exercised its enforcement discretion with respect to these claims, the claims are unauthorized and cause Defendants' products to be misbranded foods within the meaning of the Act, 21 U.S.C. § 343(r)(1)(B).

29. Subsequent to Plaintiff notifying Defendants in November 2007 that it intended to file this suit, Defendants removed many of the claims referenced above from their Brownwood Acres, FruitFast, Blueberry Power, and Flavonoid Sciences websites, removed the cold links to the Fruit Institute website, and replaced the former content of the Fruit Institute website with a page stating that the site was now "under construction."

30. Defendants also have distributed and may continue to distribute a brochure titled "Fruit Fast." The brochure lists the alleged therapeutic benefits of Defendants' tart cherry, pomegranate, and wild blueberry juice concentrates, and states that customers can "visit [www.fruitinstitute.org](http://www.fruitinstitute.org) for additional information on a variety of fruit" to "learn more about the benefits of fruit."

31. Defendants have distributed and may continue to distribute another brochure titled "Whole Fruits." The brochure has been available as part of a display for

Defendants' Cherry Flex and Wild Blueberry IQ soft gel capsules in a Michigan retail establishment and has been shipped interstate to customers upon request for additional information.

32. The Whole Fruits brochure contains various claims that Defendants' products may cure, mitigate, treat, and/or prevent various diseases such as cancer, arthritis, gout, Alzheimer's disease, and heart disease. These claims are set forth in detail in paragraph 36 below.

33. The claims on the Whole Fruits brochure referred to in paragraph 32 and detailed in paragraph 36 below cause Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

34. The Whole Fruits brochure lists the Fruit Institute's website and toll-free phone number.

35. The labels on some of Defendants' products, including but not limited to Defendants' fruit juice concentrates, fruit soft gels, and fruit supplement bars, refer to the Fruit Fast website which, prior to November 2007, then referred customers to the claims on the Fruit Institute website.

36. Defendants' current or former claims that their products may cure, mitigate, treat, prevent, and/or reduce the risk of various diseases including, but not limited to, cancer, diabetes, arthritis, gout, Alzheimer's disease, and heart disease are summarized in the table below:

Product	Claim	Current or Former Location of Claim	Type of Claim
cherries	"Clinical tests . . . show that ellagic Acid [naturally found in cherries] may be the most potent way to prevent cancer"	Fruit Institute website	drug
	"Chemicals Found in Cherries May Help Fight Diabetes"	Fruit Institute website	drug
	"Today thousands of people depend on the anti-inflammatory properties found in Tart Cherries to treat their Arthritis and Gout symptoms"	Fruit Institute website	drug
	"it is possible that the same enzymes that make cherries effective in blocking the pain messages carried by the COX enzyme would also make cherries effective in protecting against heart attack and stroke."	Fruit Institute website	drug
	"Studies show naturally-occurring compounds in tart cherries . . . may help gout, arthritis and inflammation sufferers."	Whole Fruits brochure	drug
	"New studies . . . suggest that tart cherries may reduce the risk of colon cancer because of the anthocyanins and cyanidin contained in the cherry."	Fruit Institute website	unauthorized health claim
	"Cancer-Fighter Perillyl Alcohol Found in Tart Cherries. . . . Tart cherries contain perillyl alcohol (POH), a natural compound that is extremely powerful in reducing the incidence of all types of cancer . . . 'It works on every kind of cancer we've tested against.' Perillyl alcohol (POH) has performed favorably in the treatment of advanced carcinomas of the breast, prostate and ovary."	Fruit Institute website	drug

blueberries	"Antioxidants are important in terms of their ability to protect against oxidative cell damage that can lead to conditions like Alzheimer's, cancer and heart disease - conditions also linked with chronic inflammation. The antioxidant and anti-inflammatory effects of blue-purple foods like Wild Blueberries may have the potential to help prevent these diseases"	Fruit Institute website	drug
	"Blueberries may help prevent a leading cause of blindness . . . director of the USDA studies that ranked blueberries #1 in antioxidant activity plans to study the ability of blueberries to prevent macular degeneration, a disease of the retina and the leading cause of blindness in people over age 65."	Fruit Institute website	drug
	"blueberries may help prevent urinary tract infections"	Fruit Institute website	drug
	"Research shows that Wild Blueberry compounds may inhibit cancer."	Fruit Institute website	drug
	"[Wild blueberries] may protect against oxidative cell damage that can lead to Alzheimer's, cancer and heart disease."	Whole Fruit brochure	drug
	"Wild blueberries may help protect arteries, reduce risks from cardiovascular disease."	Fruit Institute website	unauthorized health claim
	"A new study . . . found that drinking pomegranate juice can fight prostate cancer."	Fruit Institute website	drug
	"According to results [of a study], subjects who drank 180ml (6 oz.) of pomegranate juice per day for three months experienced a reduced risk for atherosclerosis, a condition that leads to arterial wall thickening and hardening"	Fruit Institute website	unauthorized health claim
	"While there's still a lot we don't know about [Alzheimer's] disease, there is some research suggesting a role for fruits, vegetables and juices in reducing risk" (on page with articles regarding the benefits of pomegranates).	Fruit Institute website	unauthorized health claim
	pomegranates		

raspberries	"Clinical tests . . . show promising results that ellagic acid [found in raspberries] . . . may help prevent cancer, inhibit the growth of cancer cells, and arrest the growth of cancer in subjects with a genetic predisposition for the disease."	Fruit Institute website	drug
	"Researchers are currently linking anthocyanin [which acts as pigment to give berries their color] activity to . . . controlling diabetes [and] . . . preventing cancer . . ."	Fruit Institute website	drug
	"Clinical tests . . . show that Ellagic Acid [found in red raspberries] inhibits the growth of cancer cells, and arrests the growth of cancer in subjects with a genetic predisposition for the disease."	Whole Fruit brochure	drug
cranberries	"The most recent research study published from Finland indicates that the anthocyanins in red raspberries help reduce the risk of heart disease."	Fruit Institute website	unauthorized health claim
	"These preliminary results suggest that cranberry may be beneficial in the prevention of peptic ulcers . . ."	Fruit Institute website	drug
	"Flavonoids . . . may reduce the risk of atherosclerosis. Cranberries contain significant amounts of flavonoids . . ."	Fruit Institute website	unauthorized health claim
grape juice	"Purple grape juice seems to have the same effect as red wine in reducing the risk of heart disease."	Fruit Institute website	unauthorized health claim
liquid glucosamine (Syn-flex 1500)	"Liquid glucosamine found in Syn-flex 1500 is one of the most effective osteoarthritis formulas on the market today."	Brownwood Acres website	drug
	"Glucosamine is clinically proven to be highly beneficial in the treatment of osteoarthritis."	Brownwood Acres website	drug
	"Glucosamine found in Syn-flex not only slows the progression of your arthritis and eases your pain, it also is able to aid in rehabilitating deteriorated cartilage and reduce inflammation."	Brownwood Acres website	drug

<p>Omega-3 fatty acids (found in Alaskan Sockeye salmon oil capsules)</p>	<p>"Studies in animals suggest that the Omega-3s may have a role in the prevention of some forms of cancer such as breast, prostate and bowel (colon) cancer."  "The anti-thrombotic properties of the Omega-3 can help reduce the risk of this type of stroke."  "Fish consumption was associated with a reduced risk of dementia and especially Alzheimer's disease."</p>	<p>Int'l Cod Liver Omega-3 Foundation website</p>	<p>drug</p>
	<p>"ADHD, or Attention-Deficit Hyperactivity Disorder, is a surprisingly common condition, with something like 3-5% of American and British children affected to some degree . . . Sufferers have recently been shown to have low blood levels of the long chain Omega-3s . . . A research study published in 2002 has shown significant benefit from a supplement of Omega-polyunsaturates."</p>	<p>Int'l Cod Liver Omega-3 Foundation website</p>	<p>unauthorized health claim</p>
	<p>"The accumulation of findings suggest that Omega-3s work in several ways to reduce heart attack risk: Anti-thrombotic. Help reduce platelet aggregation (the clumping together of red corpuscles that can form a potentially fatal blood clot in coronary arteries) . . . Arrhythmia prevention. Help protect against heartbeat abnormalities . . . that appear to be the lethal part of a heart attack . . . Blood pressure is lowered slightly by Omega-3, which reduces risk of a heart attack."</p>	<p>Int'l Cod Liver Omega-3 Foundation website</p>	<p>unauthorized health claim</p>
		<p>Int'l Cod Liver Omega-3 Foundation website</p>	<p>drug</p>

## INTERSTATE COMMERCE

37. Defendants distribute their products to customers via the Internet throughout the United States (approximately 90% of Internet sales for both Brownwood Acres and Cherry Capital are outside of Michigan). Approximately 20-25% of both companies' sales are to a wholesaler in Indiana who then distributes the products outside the state of Indiana.

## DEFENDANTS' VIOLATIONS

38. Defendants have been and may still be engaged in making claims that their products cure, mitigate, treat, prevent and/or reduce the risk of various diseases. Specifically, Defendants have promoted the use of their products in their Whole Fruit brochure and on websites owned and controlled by or related to Defendants for the cure, mitigation, treatment, prevention and/or reduction of risk of various diseases including, but not limited to, cancer, diabetes, arthritis, gout, Alzheimer's disease, and heart disease.

39. Many of Defendants' products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), because the products' labeling, including the Whole Fruit brochure and recent claims on Defendants' websites and other websites under Defendants' direction and control, establishes that Defendants' products are intended to be used in the cure, mitigation, treatment, and/or prevention of disease.

40. Defendants' products are new drugs within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as

safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

41. There is not now, nor has there ever been, an approved new drug application or an abbreviated new drug application on file with the FDA for any of Defendants' products, nor do Defendants' products qualify for an exemption as investigational new drugs. Accordingly, Defendants' products are unapproved new drugs, within the meaning of 21 U.S.C. § 355.

42. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for use and, as unapproved new drugs, they are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

43. Defendants' products are misbranded foods within the meaning of 21 U.S.C. § 343(r)(1)(B), because their labeling, specifically recent claims on the Fruit Institute website that the products may reduce the risk of certain diseases, contains unauthorized health claims.

#### HISTORY

44. Defendants have been notified by FDA on several occasions that the claims made for their products cause their products to be unapproved new drugs and their distribution in interstate commerce of unapproved new drugs violates the Act. FDA issued a Warning Letter on October 17, 2005, to Defendant de Tar, advising him that claims made for Brownwood Acres' juice concentrates and soft gel capsules on the Brownwood Acres website caused the products to be unapproved new drugs in violation of the Act.



45. FDA issued a Warning Letter on October 17, 2005, to Defendant Robert Underwood, advising him that claims made for Cherry Capital's CherryFlex and Wild Blueberry IQ products on the Flavonoid website caused the products to be unapproved new drugs in violation of the Act.

46. By letters to Defendants de Tar and Underwood dated June 20, 2006, FDA reiterated that they violated the Act by making drug claims for their products on the Brownwood Acres and Flavonoid websites. In these letters, FDA also provided written guidance to Defendants regarding the nature of health claims that can legally be made for food products as well as the process for making such claims.

47. FDA notified Defendant de Tar again on December 6, 2006, that Defendants violated the Act by making drug claims for their products on the Brownwood Acres website and provided guidance regarding the process for making health claims in compliance with the Act.

48. By letter dated July 20, 2007, FDA again notified Defendants, through their counsel, that Brownwood Acres and Cherry Capital were still violating the Act by associating the sales of their products with related web sites (i.e., [www.fruitinstitute.org](http://www.fruitinstitute.org)).

49. Only when Plaintiff notified Defendants in November 2007 that a lawsuit soon would be filed did Defendants remove many of the claims detailed above.

50. Defendants' history of promoting products to cure, mitigate, treat, prevent, and/or reduce the risk of diseases including, but not limited to, cancer, diabetes, arthritis, gout, Alzheimer's disease, and heart disease, demonstrates their unwillingness to comply with the Act. Based on Defendants' most recent course of conduct, it is evident that, unless restrained by order of this Court, Defendants will again distribute

unapproved new drugs, misbranded drugs, and misbranded foods in violation of the Act, 21 U.S.C. § 331(a) and (d).

WHEREFORE THE PLAINTIFF PRAYS:

I. That Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined from directly or indirectly: (a) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 331(d); (b) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce misbranded drugs in violation of 21 U.S.C. § 331(a); and (c) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce misbranded foods in violation of 21 U.S.C. § 331(a); and

II. That Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until: (a) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) or (j) is effective with respect to the product; (b) an effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; (c) the product's claims comport with an authorized health claim set forth in 21 C.F.R. § 101.72-101.83; (d) Defendants have received a letter of enforcement

discretion for a qualified health claim from FDA for that product; or (e) Defendants have (i) removed all claims from Defendants' product labels, labeling, promotional materials, websites owned or controlled by Defendants, and in any other media that cause that product to be a drug and/or contain unapproved or unauthorized health claims within the meaning of the Act and have (ii) removed, from their product labels, labeling, promotional materials, and websites owned or controlled by Defendants, references to or endorsements of any other website that conveys information about Defendants' products that cause those products to be a drug and/or contain unapproved or unauthorized health claims within the meaning of the Act; and

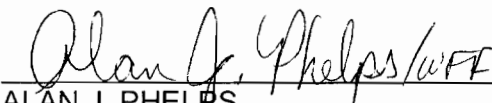
III. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED: February 12, 2008.

Respectfully submitted,

CHARLES R. GROSS  
United States Attorney for the  
Western District of Michigan

  
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