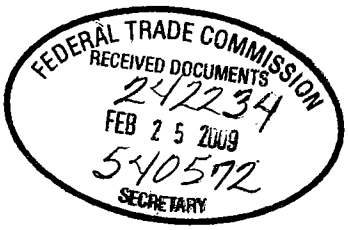
ORIGINAL



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	
DANIEL CHAPTER ONE, **a corporation, and**	**Docket No. 9329**
JAMES FEIJO, **individually, and as an officer of** **Daniel Chapter One.**	**PUBLIC DOCUMENT**

COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

Pursuant to Section 3.24 of the Commission's Rules of Practice, Complaint Counsel move for summary decision in this matter. Based on the pleadings and other evidence in the case, as described in Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Dispute, Complaint Counsel are entitled to summary decision as to violations of Sections 5(a) and 12 of the Federal Trade Commission Act. The arguments supporting Complaint Counsel's motion are set forth in the accompanying Memorandum in Support of Complaint Counsel's Motion for Summary Decision.

Respectfully submitted,

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Federal Trade Commission
Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
New York, NY 10004

Dated: February 24, 2009

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
DANIEL CHAPTER ONE, **a corporation,**	)	**Docket No. 9329**
JAMES FEIJO, **individually, and as an officer of** **Daniel Chapter One.**	)	**PUBLIC DOCUMENT**

MEMORANDUM IN SUPPORT OF COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

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MEMORANDUM IN SUPPORT OF COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

I. INTRODUCTION

The uncontroverted evidence demonstrates that Respondents Daniel Chapter One ("DCO") and James Feijo violated Sections 5(a) and 12 of the Federal Trade Commission Act (the "FTC Act") when marketing their Bio*Shark, 7 Herb Formula, GDU, and BioMixx products (collectively, the "DCO Products"). Respondents represented in their advertisements and promotional materials that the DCO Products were effective in preventing, treating, or curing cancer or tumors without competent and reliable scientific evidence to support such claims. Respondents preyed upon desperate, sick consumers "suffer[ing] from any type of cancer." Respondents touted the DCO Products as "Cancer solutions" that would "stop tumor growth," "fight[] tumor formation," and otherwise "battle[] cancer." At the time they made these serious health claims, Respondents lacked a reasonable basis for their representations, making them unsubstantiated and misleading.

Complaint Counsel have presented overwhelming uncontroverted evidence that Respondents made the alleged claims and lacked adequate substantiation. No genuine issues of material fact remain and summary decision is appropriate.

II. STATEMENT OF FACTS[1]

A. DCO and the Feijos Have Long Sold Various Products to Consumers.

In 1986, James Feijo and his wife Patricia started DCO as a health food store. CCSF ¶¶ 4 and 6. Then, in 2002, James Feijo organized DCO as a corporation sole under Washington state laws. CCSF ¶ 1. DCO currently offers consumers 150 to 200 products. CCSF ¶ 7. James Feijo serves as DCO's Overseer, trustee for all DCO assets, and custodian of DCO's financial records. CCSF ¶¶ 2, 9, and 13-14. Patricia Feijo is DCO's Secretary. CCSF ¶ 3. Neither James nor Patricia Feijo is a doctor or research scientist. CCSF 114.

Respondents' principal office and place of business is located in Portsmouth, Rhode Island, where the Feijos live. CCSF ¶ 5. DCO's two Rhode Island buildings contain an Order Center and a warehouse for the products that DCO offers to the public. CCSF ¶ 17. James Feijo established another Washington corporation sole -- Messiah Y'Shua Shalom -- which he uses to own the Rhode Island property. CCSF ¶¶ 19-20. DCO also owns a three-bedroom property in Deerfield Beach, Florida, where the Feijos stay, as well as two Cadillacs which the Feijos use. CCSF ¶¶ 22-24. DCO pays for all the Feijos' expenses. CCSF ¶¶ 15, 23, and 25.

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[1] Pursuant to Rule of Practice § 3.24(a), Complaint Counsel have submitted the accompanying Statement of Material Facts As To Which There Is No Genuine Issue ("CCSF") as a separate document. Complaint Counsel reserves the right to supplement the CCSF and the exhibits to this Motion. Respondents refused to respond to discovery requests, which resulted in the Court granting Motions to Compel. Respondents did not respond to the outstanding discovery requests until after the close of business on February 23, 2009, the day before Motions for Summary Decision were due.

B. The Feijos are Responsible for the Development and Price of the DCO Products.

1. The Feijos Developed the DCO Products and Their Labels.

James Feijo developed, created, and produced the DCO Products. CCSF ¶ 8. He established the DCO Products' price. CCSF ¶ 37. He and Patricia Feijo have been solely responsible for creating, drafting, and approving the DCO Products' directions and recommended usages. CCSF ¶ 95. They also developed the suggested dosages. CCSF ¶¶ 95, 98, 100, and 102. The identity and amount of each ingredient is contained on the product labels. CCSF ¶ 96. DCO contracts with Universal Nutrition to manufacture approximately 35-40 products, including Bio*Shark, GDU, and BioMixx. CCSF ¶ 82.

2. Respondents Sell Products to Consumers.

Over a thousand consumers have purchased DCO's products. CCSF ¶ 46. DCO has generated approximately $2 million in annual sales for 2006, 2007, and 2008. CCSF ¶ 47. DCO offers consumers coupons for their next online store order. CCSF ¶ 60. Respondents run promotions from time to time to "give [consumers] more of an opportunity to . . . get things at a lower rate." CCSF ¶ 61. For example, consumers can buy multiple bottles and get a bottle free. CCSF ¶ 62. DCO charges shipping and handling fees of $20.95. CCSF ¶ 59. Doctors and stores that carry DCO's product line purchase the products at a lesser price. CCSF ¶ 64. DCO sells its products in a number of stores nationally, including stores in Georgia and Pennsylvania. CCSF ¶ 63.

The DCO Products are expensive. An FTC investigator, Michael Marino, purchased one bottle of each of the four DCO Products, which together cost $175.75. CCSF ¶¶ 52 and 58. With his purchase, he received a product catalog, a blank purchase order form, and an invoice

form. CCSF ¶ 55. At least one consumer pleaded for prices to be lowered: "There should be discounts for customers who have referred lots of people and for those customers who consume lots of product monthly." CCSF ¶ 73. To counter such complaints, on their Web site, Respondents post "testimonials" to convince consumers to pay their high prices: "[i]t wasn't cheap but it was the best money I ever spent"; "I then proceeded to reduce my 7 Herb Formula to a maintenance dosage. Tricia & Jim Feijo did not agree with my decision. They felt I should stay on the maximum dosage to be safe, but I was having financial problems, and could not afford the cost." CCSF ¶¶ 71-72.

3. The DCO Products.

a. Bio*Shark

Bio*Shark contains, among other ingredients, Shark Cartilage. CCSF ¶ 76. Each Bio*Shark label directs users to take 2-3 capsules three times a day or as directed by a physician or by a "BioMolecular Nutrition health care professional." CCSF ¶ 97. Respondents invented the term BioMolecular Nutrition to describe "the spiritual and physical" aspects of their products. CCSF ¶¶ 26-27. Respondents offer one bottle of Bio*Shark for $30.95 (100 capsules) and $65.95 (300 capsules), but only pay Universal Nutrition, their manufacturer, $3.15 per unit for the 100-capsule and $8.75 per unit for the 300-capsule bottle of Bio*Shark. CCSF ¶¶ 77-78. Thus, their acquisition cost for the 100-capsule bottle is approximately 10 percent of what Respondents charge consumers. During 2008, Respondents paid Universal Nutrition approximately $1,437 to manufacture 479 100-capsules bottles of Bio*Shark and approximately $6,256 to manufacture 782 300-capsule bottles of Bio*Shark. CCSF ¶ 79.

b. 7 Herb Formula

7 Herb Formula, a liquid tea concentrate, contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. CCSF ¶ 84. Respondents' label directs users to take 1-2 ounces of 7 Herb Formula with 2-4 ounces of hot or cold filtered or distilled water. CCSF ¶ 99. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition health care professional. CCSF ¶ 99.

Respondents offer one 32-ounce bottle of 7 Herb Formula for $70.95. CCSF ¶ 85. Their acquisition cost for 7 Herb Formula is approximately 30 percent of the price they charge to consumers. CCSF ¶ 45.

c. GDU

GDU contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. CCSF ¶ 87. Respondents' label directs users to take 3-6 capsules 2 to 4 times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. CCSF ¶ 101.

Respondents offer GDU for $29.95 (120 capsules) and $45.95 (300 capsules) but only pay Universal Nutrition $3.28 for the 120-capsule bottle and $7.07 for the 300-capsule bottle of GDU. CCSF ¶¶ 88-89. Thus, their acquisition cost for the 120-capsule bottle is slightly over 10 percent of what they charge consumers. During 2008, Respondents paid Universal Nutrition approximately $5,127 to manufacture 1,709 of the 120-capsule bottles and approximately $52,661 to manufacture 7,523 of the 300-capsule bottles of GDU. CCSF ¶ 90.

d. BioMixx

BioMixx contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. CCSF ¶ 91. Respondents' label for BioMixx directs users to take five scoops daily. CCSF ¶ 103.

Respondents offer BioMixx for $22.95 (1 lb. powder) and $40.95 (3 lb. powder), but only pay Universal Nutrition $11.50 for the 3-pound bottle of BioMixx, CCSF ¶¶ 92-93, approximately 35% of what they charge consumers. During 2008, Respondents paid Universal Nutrition approximately $8,778 to manufacture 798 3-pound bottles of BioMixx. CCSF ¶ 94.

C. Respondents Disseminate Claims That the DCO Products "Fight Cancer," "Stop Tumor Growth," and Are a "Cancer Solution" For All Types of Cancer.

Respondents' Web sites www.danielchapterone.com, dc1pages.com, www.7herbformula.com, www.gdu2000.com, and dcstore.com provide information on the DCO Products. CCSF ¶ 141-42. Consumers can locate the Web site www.danielchapterone.com by entering the term "cancer" in a Google search. CCSF ¶ 144. Respondents also disseminate information about the DCO Products through written materials, including the BioGuide, the Cancer Newsletter, and the radio program "Daniel Chapter One Health Watch." CCSF ¶ 142. The Feijos are responsible for the information disseminated about the DCO Products. CCSF ¶ 143. James and Patricia Feijo also co-host DCO's radio program for two hours a day, Monday through Friday. CCSF ¶ 146. They have counseled cancer patients who have called into the radio program about taking the DCO Products. CCSF ¶ 147. Respondents purposefully use the DCO radio program and the DCO Web sites to reach out to consumers. CCSF ¶ 148.

On their Web sites, radio program, and in their other publications, Respondents make numerous claims about how their products are a "Cancer Solution," a "Cancer Treatment," or can be used for "all types of cancer" to "fight cancer," "stop tumor growth," "fight tumor formation," "battle cancer," and "digest . . . unwanted tumors." CCSF ¶¶ 104-06, 124-25, 132.

1. Claims That the DCO Products Are For All Types of Cancer.

Respondents recommend taking the DCO Products "**If you suffer from any type of cancer**," CCSF ¶¶ 120, 124, 133, and 138 (emphasis added) and, in their *The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide*, recommend the DCO Products for "***All types of Cancer***:" CCSF ¶ 106. Respondents reinforce this claim by listing at least ten different types of cancer with consumer "testimonials." CCSF ¶ 107.

2. Claims That the DCO Products Will Fight Cancer.

The DCO Products all appear in Respondents' Cancer Newsletter, *How to Fight Cancer is Your Choice!!!*. CCSF ¶ 111. Respondents describe the DCO Products as a "Cancer solution" and specifically advise consumers to take the DCO Products to "fight" or "battle" cancer:

> **If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it:** [emphasis added]
> 7*Herb Formula ™. . .
> Bio*Shark ™. . .
> BioMixx ™. . .
> GDU Caps ™. . .
> [depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
> **Daniel Chapter One's Cancer solutions**
> To Buy the products click here
> **How to fight cancer is your choice!**. . . [emphasis added]
> CCSF ¶ 124.

Respondents use testimonials to convince consumers that the DCO Products will help them "fight" and "battle" cancer and end up in remission, claiming that one consumer had "three inoperable tumors," and that, when she "decided not to do chemotherapy or radiation, my *father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng and BioShark.'" "I am now in complete remission. . ."* CCSF ¶ 108 (*italics added).* Similarly, another testimonial

claimed that 7 Herb Formula "did such a good job fighting cancer," "I plan to stay on that forever!" CCSF ¶ 127.

On their radio program, DCO Healthwatch, Respondents tout the DCO Products. By example, on one show Patricia Feijo urged consumers:

> "[W]hile the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. **The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer.**" CCSF ¶ 118. (emphasis added)

3. Claims that the DCO Products will Fight and Stop Tumors.

Respondents also specifically claim that the DCO Products will "battle tumors," "stop tumor growth," "fight tumor formation," and "digest . . . unwanted tumors." CCSF ¶¶ 122, 124, 128, and 132. On danielchapterone.com and dc1pages.com, Respondents advise consumers that: "With Jim Feijo's addition to the [7 Herb] formula, **we now have the most effective and potent formula available in the battle against tumors.**" (emphasis added) CCSF ¶ 128. In their product catalog and on their Web site, Respondents claim that the 7 Herb Formula will "fight pathogenic bacteria and tumor formation." CCSF ¶¶ 124 and 126. Similarly, in their product catalog, Respondents claim that GDU "[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein, ***even that of unwanted tumors*** and cysts. Helps to relieve pain, inflammation, and as ***an adjunct to cancer therapy***." (emphasis added). CCSF ¶¶ 132 and 134. They likewise claimed that their "**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks," (emphasis in original), a claim repeated in their product catalog. CCSF ¶¶ 121-22. Respondents also used a testimonial in their product catalog to claim that BioMixx, 7 Herb Formula, and Bio*Shark worked on "three inoperable tumors" so well that one "just

above the brain stem . . . has completely disappeared," one on the liver "is shrinking," and one behind the heart "has shrunk over 50%." CCSF ¶ 108.

III. SUMMARY DECISION SHOULD BE GRANTED WHEN, LIKE HERE, THERE IS NO GENUINE ISSUE FOR TRIAL.

Commission Rule 3.24(a)(2) provides that summary decision "shall be rendered . . . if the pleadings and any depositions, answers to interrogatories, admissions on file, and affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to such decision as a matter of law." 16 C.F.R. § 3.24(a)(2). Rule 3.24(a)(2) is applied consistent with case law interpreting the summary judgment standard set out in Federal Rule of Civil Procedure 56. *In re Kroger Co.*, 98 F.T.C. 639, 726 (1981); *In re Hearst Corp.*, 80 F.T.C. 1011, 1014 (1972).

Whether an advertising practice complies with the laws or regulations the FTC enforces is a question of law that the Court can resolve on summary decision. *FTC v. Bronson Partners*, 564 F. Supp. 2d 119 (D. Conn. 2008) (ruling on summary judgment that defendants violated the FTC Act by making deceptive claims to consumers in advertisements for a purported weight-loss product); *FTC v. Nat'l Urological Group, Inc.*, No.1:04-CV-3294, 2008 U.S. Dist. LEXIS 44145 (N.D.Ga. June 4, 2008) (ruling on summary judgment that defendants violated the FTC Act by making deceptive claims to consumers in advertisements for dietary supplements); *FTC v. Natural Solution, Inc.*, No. 06-6112, 2007 U.S. Dist. LEXIS 60783 (C.D.Cal. Aug. 7, 2007) (ruling on summary judgment that defendants violated the FTC Act by making deceptive claims to consumers in advertisements for a dietary supplement purported to prevent and treat cancer).

The party moving for summary judgment bears the initial burden of identifying evidence that demonstrates the absence of any genuine issue of material fact. *Green v. Dalton*, 164 F.3d

671, 675 (D.C. Cir. 1999) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Once the moving party has properly supported its motion for summary judgment, the nonmoving party must "do more than simply show there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The nonmoving party may not rest on mere allegations or denials of its pleading but must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 587 (quoting Fed. R. Civ. P. 56(e)). *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986); 16 C.F.R. § 3.24(a)(3). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Matsushita* 475 U.S. at 587 (citation omitted). Thus, the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Liberty Lobby,* 477 U.S. at 247-48.

There is no genuine issue as to any material fact relating to: (1) whether Respondents made the representations challenged in the Complaint and (2) whether these representations were unsubstantiated and misleading in a material respect. Thus, Complaint Counsel is entitled to summary decision as a matter of law.

IV. RESPONDENTS DISTRIBUTE THEIR PRODUCTS IN COMMERCE

A. The FTC Has Jurisdiction Over Even Ostensibly Nonprofit Entities Engaging in For-Profit Activities.

Under Section 5 of the FTC Act, the FTC is "empowered and directed" to prevent unfair or deceptive practices in commerce by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(2). "Corporations" are defined in Section 4 of the FTC Act as "any company . . . which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44.

"Courts have consistently recognized that the [FTC] Act applies to 'corporations' organized for profit regardless of the form of their charter or statutory source." *FTC v. Ameridebt, Inc.*, 343 F. Supp. 2d 451, 460 (D. Md. 2004) (citing *Community Blood Bank v. FTC*, 405 F.2d 1011, 1018-20 (8th Cir. 1969)). *See also FTC v. Nat'l Comm'n on Egg Nutrition*, 517 F.2d 485, 488 (7th Cir. 1975) (affirming jurisdiction over trade group organized for the profit of its members). Furthermore, courts have long held that non-profit corporations are not exempt from the reach of the FTC Act. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 769 (1999); *Nat'l Comm'n on Egg Nutrition*, 517 F.2d at 489; *Community Blood Bank*, 405 F.2d at 1017; *Ameridebt, Inc.*, 343 F. Supp. 2d at 451.

As the Court noted in *California Dental Association*, "the logic and purpose of the FTC Act comports" with the notion that the FTC can sometimes have jurisdiction over ostensibly non-profit entities, which often "have the same capacity and derivatively, at least, the same incentives as for-profit organizations to engage in unfair methods of competition or unfair and deceptive acts" and may even have "certain advantages" because "[they] would enjoy the screen of superficial disinterest while devoting itself to serving the interests" of its for-profit affiliates. 526 U.S. at 769.

Here, Respondents are engaged in for-profit activities. Respondents charge consumers three to ten times what it costs them to purchase the DCO Products from manufacturers. *See* pp. 5-6, *supra*. They charged FTC Investigator Marino $175.75 for the four DCO Products. CCSF ¶¶ 52 and 58. Moreover, Respondents even run an affiliate sales program, and advise those who want to join this program of the sales and profits they too can make. CCSF ¶ 70. On their Web site, Respondents also place a "™" next to their products, indicating that their products are trademarked, so as to protect DCO from having its brand (and profits) dilated.

Moreover, the profits generated by the sale of DCO products allow DCO to own two houses used by the Feijos, to own two Cadillacs used by Feijos, and to pay all the Feijos living expenses. CCSF ¶¶ 5,15, and 22-25.

B. Respondents Are Engaged in Commerce.

Respondents admit that they distribute the DCO Products in commerce, CCSF ¶ 30, an admission borne out by their activities. Nationwide advertising, marketing, or sales activity constitutes "commerce" under the FTC Act. *See, e.g., P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *see, e.g., Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities). Respondents engage in nationwide advertising, marketing, *and* sales activity.

First, Respondents advertise their products on their Web sites and on their Radio Show. CCSF ¶¶ 104-05, 117-18, 122, 128-31, and 136. Next, DCO has a toll-free telephone number and a call center for consumers to purchase the DCO Products. CCSF ¶ 31. DCO's toll-free number is advertised on DCO's Web site, "BioGuide," radio program, and on the front page of DCO's BioMolecular Nutrition Product Catalog, where Respondents inform consumers to "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." CCSF ¶¶ 31-33, and 36. DCO's Order Center is open Monday through Friday from 9:00 a.m. to 8:00 p.m., and receives payments through credit card and COD. CCSF ¶¶ 40-41. DCO also accepts consumers' orders on the Internet. CCSF ¶ 42. DCO's Web site invites consumers to shop at DCO's "On-Line Store" and to "Buy Now." CCSF ¶¶ 43-44. In addition, a number of stores nationally sell DCO's products. CCSF ¶ 63. Over one thousand consumers have purchased

DCO's products. CCSF ¶ 46. DCO has generated $2 million in annual gross sales for each of the last several years. CCSF ¶ 47.

Thus, regardless of how Respondents may attempt to hide their conduct from scrutiny, the uncontroverted facts firmly establish DCO's distinctly for-profit nature, and as engaging in commerce, placing Respondents squarely within the jurisdiction of the FTC Act.

V. RESPONDENTS' DECEPTIVE ADVERTISING VIOLATES SECTIONS 5 AND 12 OF THE FTC ACT.

The undisputed evidence shows that Respondents engaged in unfair or deceptive acts or practices prohibited by Sections 5 and 12 of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2).[2]

An advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (citing Sections 5 and 12); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D.Mass 2000); *Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Thompson Medical Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Cliffdale Assocs. Inc.*, 103 F.T.C. 110, 164-66 (1984); *FTC Policy Statement on Deception*, 103 F.T.C. 174 (1984) (appended to *Cliffdale Assocs.*).

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[2] For the purposes of Section 12, the DCO Products are "food" or "drugs." 15 U.S.C. § 55(a), (b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). Section 12 defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.

In implementing the "likely to mislead" standard, "the [FTC] examines the overall net impression of an ad[vertisement] and engages in a three-part inquiry: (1) what claims are conveyed in the advertisement; (2) are those claims false or misleading; and (3) are those claims material to prospective consumers." *Kraft*, 970 F.2d at 314.

A. Respondents Represented in Their Advertisements that Their Products Prevent, Treat, and/or Cure Cancer.

1. The Appropriate Legal Standard Is the Overall Net Impression Created by the Advertisement.

The FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See Kraft*, 970 F.2d at 318 ("[i]n determining what claims are conveyed by a challenged advertisement, the [FTC] relies on . . . its own viewing of the ad"); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965). In determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *Stouffer Foods Corp.*,118 F.T.C. 746, 799 (1994); *Kraft*, 114 F.T.C. 40 at 122 (1991); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 688 (3d Cir. 1982); *FTC Policy Statement on Deception*, 103 F.T.C. 174, 179 (1984) (appended to *Cliffdale Assocs.*) (emphasizing importance of considering "the entire mosaic, rather than each tile separately"). Features of an advertisement such as a product name, visual images, and the use of testimonials may imply claims. *Jacob Siegel v. FTC*, 327 U.S. 608, 609 (1946); *Kraft*, 114 F.T.C. at 322; *Thompson Medical*, 104 F.T.C. at 793 and 811-12; *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 301, 303 (7th Cir. 1979). To determine how "reasonable consumers" interpret a claim, the Commission considers the target market for the advertisement. When the target market consists of "desperate consumers with terminal illnesses," the FTC has shown

particular care in evaluating deceptive acts or practices. *FTC v. Travel King, Inc.*, 86 F.T.C. 715 (1975).

Advertising claims may be express or implied. *Kraft,* 970 F.2d at 318. Express claims directly state the representation at issue, while implied claims make representations without direct statements. *Id.* at 318 and 319 n.4; *Thompson Medical*, 104 F.T.C. at 788-89. The courts and the FTC have recognized consistently that implied claims fall along a continuum, from those which are so conspicuous as to be virtually synonymous with express claims, to those which are barely discernible. *See, e.g., Kraft*, 970 F.2d at 319; *FTC v. Febre*, No. 94 C 3625, 1996 WL 396117, at *4 (N.D. Ill. July 2, 1996) (magistrate judge recommendation), adopted by 1996 WL 556957 (N.D. Ill. Sept. 25, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997); *see also Bronson Partners*, 564 F. Supp. at 127-28 (an advertisement's statements were "so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims").

This Court has the authority to grant summary decision as to the conveyed meaning of advertisements and promotional materials based on a facial analysis of these advertisements or promotional materials. *Automative Breakthrough Sciences, Inc.*, Docket Nos. 9275-77, 1996 FTC LEXIS 252, at *44, (Partial Summary Decision May 22, 1996) (citing *Kroger Co.*, 98 F.T.C. at 726, 729 n.11; *Ford Motor Co.*, 87 F.T.C. 756, 794-97 (1976)). No genuine issue of material fact is created simply by Respondents disputing that the advertisements make the alleged claims. *See Kroger*, 98 F.T.C. 729 n.11; *Kraft, Inc.*, 114 F.T.C. at 120 n.8; *Automotive Breakthrough Sciences*, 1996 FTC LEXIS 252 at *43. Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft*, 114 F.T.C. at 120 n.8. "Statements susceptible of both a misleading and a truthful interpretation will be

construed against the advertiser." *Bronson Partners*, 564 F. Supp. 2d 119, 127 n.6 (D. Conn. 2008) (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

If the facial analysis demonstrates that the claims were conveyed in the advertisements and promotional materials, the Court need not consider extrinsic evidence even if such evidence is offered. *Novartis*, 127 F.T.C. 580, 680 (1996); *Stouffer*, 118 F.T.C. at 798; *Kraft, Inc.,* 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.

2. Respondents Claimed that the DCO Products Could Prevent, Treat, and/or Cure Cancer.

The Complaint alleges that Respondents represented in their advertising and promotional materials that the DCO Products were effective in preventing, treating, and/or curing cancer. As the Court noted in its February 2, 2009 Order Denying Respondents' Motion to Dismiss Complaint, Respondents admit in their Answer that they made such claims. Order Den. Resp'ts' Mot. to Dismiss, at 2; Answer ¶ 14.

In addition to Respondents' admissions, a facial analysis of the challenged DCO Products' advertisements and promotional materials establishes that the alleged representations are a reasonable interpretation. Respondents' advertisements and promotional materials for the DCO Products, which include, but are not limited to, Exhibits A-D of the Complaint, convey bold promises of cancer prevention, treatment, and cure that, if not express, are so strongly implied as to be virtually express.

a. Respondents' Advertising Represented that Bio*Shark Inhibits Tumor Growth and Is Effective in Treating Cancer.

Respondents' Web page for Bio*Shark contains both express and strongly implied representations that create the net impression that Bio*Shark inhibits tumor growth, as alleged in ¶14 a of the Complaint. Complaint Counsel's Summary Decision Exhibit (hereinafter referred to

as S.D. Ex.___) 7 at FTC-DCO 0011. In the Web page's center, in bold type, appears the headline "**Bio*Shark: Tumors & Cysts**." Respondents' decision to tie unequivocally its product with tumors and cysts carries the strong implication that Bio*Shark is intended to be used on tumors. Immediately beneath this statement, the representation is stated virtually expressly: "Pure skeletal tissue of sharks which provides a protein that **inhibits angiogenesis** -- the formation of new blood vessels. **This can stop tumor growth**, and halt the progression of eye diseases . . .". [emphasis added]. *Id.*; CCSF ¶ 119. The claim is restated even more succinctly in an underlined link near the bottom of the Web page: "**Stop Tumor Growth & Cysts**." S.D Ex. 7 at FTC-DCO 0011; CCSF ¶ 119. Another link on the same page reinforces this claim, inviting consumers to "Read our clients [*sic*] testimonies [on??] Bio Shark & Tumors." S.D. Ex. 7 at FTC-DCO 0011; CCSF ¶ 119. The link appears directly below the "BUY NOW" link through which consumers may purchase the product. S.D. Ex. 7 at FTC-DCO 0011; CCSF ¶¶ 44 and 119.

Respondents make numerous strongly implied representations that Bio*Shark is effective in the treatment of cancer as alleged in ¶ 14b of the Complaint. Respondents' representations about stopping tumor growth also support the allegation that Bio*Shark is effective in the treatment of cancer. Respondents tout Bio*Shark a "Cancer solution." CCSF ¶ 104. Respondents also state on their Web site:

> **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products[*sic*], to fight it:** . . . Bio*Shark TM. . . **How to fight cancer is your choice!"** CCSF ¶ 120 [emphasis added]

Respondents also used testimonials on their Web site and during the DCO Healthwatch radio program to make representations to consumers that Bio*Shark cured cancer or resulted in a cancer patient's remission. For example, they represented that Bio*Shark, in conjunction with 7

Herb Formula and GDU, cured someone's skin cancer so that "there was no trace of cancer," CCSF ¶ 130, very strongly implying, if not expressly stating, that Bio*Shark is effective in treating cancer. Similarly, Respondents represented that Bio*Shark, with BioMixx and 7 Herb Formula, cured three inoperable tumors, resulting in the patient's "complete remission." CCSF ¶ 125. Patricia Feijo also specifically advised a consumer who called the radio program, and whose father was diagnosed with colon cancer, that she should order Bio*Shark and the other DCO Products for her father, and a copy of the DCO publication *How To Fight Cancer Is Your Choice.* CCSF ¶¶ 36, 147.

b. Respondents Represented that 7 Herb Formula Is Effective in the Treatment or Cure of Cancer and Inhibits Tumor Formation.

As alleged in ¶14 c and d of the Complaint, Respondents expressly claim or very strongly imply that 7 Herb Formula is effective in the treatment or cure of cancer and inhibits tumor formation. As with Bio*Shark, Respondents claim on their Web site that 7 Herb Formula is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products[*sic*], to fight it:** . . . 7 Herb Formula. . . **How to fight cancer is your choice!,"** (emphasis added) CCSF ¶ 104 and 124, thus strongly implying, if not explicitly stating, that 7 Herb Formula is effective in the treatment or cure of cancer.

Respondents also use testimonials on their Web site and in their radio program to convince consumers that 7 Herb Formula (and some combination of the other three DCO Products): (1) "battles cancer," resulting in a patient's "complete remission" despite "inoperable tumors"; (2) does "such a good job fighting cancer" that a patient "plan[s] to stay on [7 Herb Formula] forever" because it is a "good prophylaxis," or (3) cured someone's skin cancer so that "there was no trace of cancer," thus strongly implying, if not expressly stating, that 7 Herb

Formula effectively treats, cures, or prevents cancer. CCSF ¶¶ 125, 127, and 130.

On their Web sites, Respondents advise consumers that: "With Jim Feijo's addition to the [7 Herb] formula, **we now have the most effective and potent formula available in the battle against tumors.**" (emphasis added) CCSF ¶ 128. In their product catalog and Web site, Respondents claim that the 7 Herb Formula will "fight . . . tumor formation," CCSF ¶¶ 124 and 126, (under the heading "Cancer News"), thus strongly implying, if not explicitly stating, that 7 Herb Formula inhibits tumor formation (and thus prevents cancer or the recurrence of cancer).

Respondents also strongly imply, if not explicitly claim, that 7 Herb Formula (and other DCO Products) inhibit tumor formation when they use a testimonial in their product catalog to claim that BioMixx, 7 Herb Formula, and Bio*Shark worked on "three inoperable tumors" so well that one "just above the brain stem . . . has completely disappeared," one on the liver "is shrinking," and one behind the heart "has shrunk over 50%." CCSF ¶ 108.

c. Respondents Represented that GDU Eliminates Tumors and Is Effective in the Treatment of Cancer.

As alleged in ¶14 e and f of the Complaint, Respondents expressly claim or very strongly imply that GDU eliminates tumors and is effective in the treatment of cancer. Respondents' description of GDU on the DCO Web site leads with the statement "[GDU] [c]ontains natural proteolytic enzymes (from pineapple source bromelain) **to help digest** protein – even that of **unwanted tumors** and cysts." CCSF ¶ 132 (emphasis added). This statement strongly implies that GDU's enzymes eliminate tumors by eroding their protein. In addition, the advertisement expressly states that "GDU is also used . . . as an adjunct to cancer therapy." CCSF ¶ 132. The Web page also features a link to "[r]ead our clients[*sic*] testimonials," which include stories about sufferers of prostate cancer and a breast mass. S.D. Ex. 7 at FTC-DCO 0029.

As with DCO's other Products, Respondents claim on their Web site that GDU is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [*sic*], to fight it:** . . . GDU. . . **How to fight cancer is your choice!,"** CCSF ¶¶ 104, 133 [emphasis added], thus strongly implying, if not explicitly stating, that GDU effectively treats cancer.

d. Respondents Represented that BioMixx Is Effective in the Treatment of Cancer and Heals the Destructive Effects of Radiation and Chemotherapy.

As alleged in ¶14 g and h of the Complaint, Respondents expressly claim or very strongly imply that BioMixx effectively treats cancer and heals the destructive effects of radiation and chemotherapy. As with DCO's other Products, Respondents claim on their Web site that BioMixx is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [*sic*], to fight it:** . . . BioMixx. . . **How to fight cancer is your choice!,"** (emphasis added) CCSF ¶¶ 104, 138, thus strongly implying, if not explicitly stating, that BioMixx effectively treats cancer. DCO's "Cancer Newsletter" contains both express claims and claims so strongly implied as to be virtually express. CCSF ¶¶ 111-12. The cover displays the following:

how to

fight

cancer is

your

choice!!!

CCSF ¶ 111; S.D. Ex. 7 at FTC-DCO 0031; S.D. Ex. 10 at FTC-DCO 0390. Inside, Respondents printed an anecdote about a man who, after taking a combination of DCO products

including 7 Herb Formula, Bio*Shark, and BioMixx, made a full recovery from bladder cancer and emphysema. S.D. Ex. 7 at FTC-DCO 0032. The newsletter also describes the BioMixx product, stating expressly that BioMixx "**is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments.**" CCSF ¶ 140; S.D. Ex. 7 at FTC-DCO 0032 (emphasis added).

In Respondents' *BioGuide*, they use a consumer testimonial which claimed that a cancer patient had three inoperable tumors and decided not to take radiation or chemotherapy but used BioMixx and other DCO Products, which resulted in "complete remission," thus making an express, or strongly implied, claim that BioMixx effectively treats cancer:

> "When I decided not to do chemotherapy or radiation, my father sent me ***BIOMIXX*** and *7 HERB FORMULA*. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic, Siberian Ginseng, and Bio*Shark. **I am now in complete remission. The cancer cell count has dropped, the doctors tell me.** I had a tumor just above the brain stem in my brain that has completely disappeared. The tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . ." (emphasis in bold added) CCSF ¶ 108.

B. Respondents' Representations That The DCO Products Prevent, Treat, or Cure Cancer Are Misleading.

1. Unsubstantiated Claims Are Misleading.

The Commission may prove an advertisement is deceptive or misleading by showing that an express or implied claim is false, or by showing that a claim is unsubstantiated because Respondents lacked a reasonable basis for asserting that the claim was true. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). Proof of intent to deceive is not required, and "the subjective good faith of the advertiser is not a valid defense to an enforcement action brought under section 5(a)." *Sabal*, 32 F. at 1007; *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

The "reasonable basis" test is an objective standard. Advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)). The Commission has the burden of proving that Respondents' purported substantiation is inadequate, but is not required to conduct or present clinical studies showing that the products do not perform as claimed. *See FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) *aff'd* 512 F.3d 858 (7th Cir. 2008), (citing *Sabal,* 32 F. Supp. 2d at 1008-09).

For health and safety claims, advertisers must possess "competent and reliable scientific evidence" substantiating their claims in order to have a "reasonable basis" for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer); *FTC v. QT, Inc.*, 448 F. Supp. at 961 ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief).

"Competent and reliable scientific evidence" is typically defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so,

using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

Courts have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of various health-related efficacy claims. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F.Supp. 2d 1263, 1274 (S.D. Fla. 1999) ("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in [the product formula]."); *Sabal*, 32 F.Supp. 2d at 1008-09 (rejecting study as valid substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Cal. Pac. Research, Inc.*, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability"); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim").

Respondents use testimonials to make representations to consumers, but courts consistently have found such anecdotal testimonial evidence inadequate to support such claims. *See, e.g., Direct Marketing Concepts*, 569 F. Supp. 2d at 304 (entering summary judgment for FTC where it was undisputed that respondents had no scientific studies supporting health-related efficacy claims, despite testimonials from customers); *FTC v. Simeon Mgmt. Corp.*, 579 F.2d 1137, 1143-44 (9th Cir. 1978) (anecdotal evidence of weight loss insufficient to support weight loss claims); *Koch v. FTC*, 206 F.2d 311, 316 (6th Cir. 1953) (evidence regarding case histories

did not support cancer claims); *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008) ("a person who promotes a product that contemporary technology does not understand must establish that this 'magic' actually works"; "[p]roof is what separates an effect new to science from a swindle" and testimonials "are not a form of proof because most testimonials represent a logical fallacy: *post hoc ergo propter hoc.* (A person who experiences a reduction in pain after donning the [Q-Ray] bracelet may have enjoyed the same reduction without it. That's why the 'testimonial' of someone who keeps elephants off the streets of a large city by snapping his fingers is the basis of a joke rather than proof of cause and effect)").

Respondents' purported substantiation is a far cry from "competent and reliable scientific evidence." Thus, Respondents did not possess a reasonable basis for their advertising representations and such representations are misleading.

2. Respondents Did Not Possess a Reasonable Basis for Their Advertising Representations that the DCO Products Prevent, Treat and/or Cure Cancer.

Respondents admit in their Answer that they represented that they possessed and relied upon a reasonable basis that substantiated the claims at issue in the Complaint. Answer ¶ 15. However, the evidence reveals that Respondents did not have a reasonable basis for their advertising claims.

a. Respondents Never Conducted Any Tests or Studies on the DCO Products.

Respondents have failed to produce any competent and reliable scientific evidence to substantiate their claims that Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx prevent, treat, or cure cancer or tumors. They have conducted no scientific testing on any of the DCO Products, and no person or entity, including Universal Nutrition, has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. CCSF ¶¶ 149-

152, 159, 162-63, 168-69, 171. Respondents have no documents relating to their policies, procedures, or requirements for evaluating or reviewing the safety, efficacy, or bioavailability for the DCO Products. CCSF ¶ 153.

b. Dr. Miller, an Expert Oncologist, Confirms that No Competent and Reliable Scientific Evidence Exists with Regard to the DCO Products.

Complaint Counsel submits the Expert Report and deposition testimony of Denis R. Miller, M.D., a board-certified pediatric hematologist/oncologist, which confirms that no competent and reliable scientific evidence substantiates Respondents' claims concerning cancer. CCSF ¶¶ 172-194. For over 40 years, Dr. Miller has directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center, and Northwestern University Medical School. CCSF ¶ 173. Dr. Miller has supervised numerous clinical studies of cancer treatments and authored hundreds of book chapters and peer reviewed articles on cancer. CCSF ¶¶ 175-76.

Dr. Miller noted that "to constitute competent and reliable scientific evidence, a product that purports to treat, cure, or prevent cancer must have its efficacy and safety demonstrated through controlled clinical studies." CCSF ¶ 178. He stated that "only data from well-designed, controlled, clinical trials will substantiate claims that a new therapy . . . is safe and effective to treat, cure, or prevent cancer." CCSF ¶ 179. Dr. Miller also noted that anecdotal reports are "the weakest form of evidence supporting the anticancer activity of a new agent," and that testimonials "do not substitute for a well-designed clinical trial." CCSF ¶¶ 180-81.

Dr. Miller concluded that "[a] thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific

evidence that [the DCO Products] are effective either alone or in combination with other DCO products in the treatment or cure of cancer, in inhibiting tumor formation, and in preventing the destructive effects of radiation and chemotherapy." CCSF ¶ 182. None of the purported experts put forth by Respondents contradicted Dr. Miller's findings.

i. Respondents' Claims that Bio*Shark Inhibits Tumor Growth and Effectively Treats Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that Bio*Shark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. CCSF ¶ 183. He stated that there were no adequate and well-controlled studies demonstrating that Bio*Shark is antiangiogenic or is effective in the treatment of cancer, and even supporting non-clinical studies of crude or partially-purified shark cartilage products were extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, and dose response. CCSF ¶ 184. In addition, Dr. Miller noted that Respondents' reliance on Dr. I. William Lane's book, *Sharks Don't Get Cancer*, was misplaced, as studies at Johns Hopkins University indicate that sharks do indeed get cancer. CCSF ¶ 185. [3]

ii. Respondents' Claims that 7 Herb Formula Inhibits Tumor Formation and Effectively Treats or Cures Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable

[3] In 2000, I. William Lane and his company Cartilage Consultants, Inc., as well as Andrew J. Lane and his company Lane Labs-USA, Inc., entered into orders to settle FTC charges that they made unsubstantiated claims about the efficacy of the products BeneFin (a shark cartilage product) and Skin Answer (a glycoalkoid product) in the prevention, treatment, and cure of cancer. *See FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (D. N.J. June 30, 200) (contempt motion pending).

scientific evidence that 7 Herb Formula inhibits tumor formation and is effective in the treatment or cure of cancer in humans. CCSF ¶ 186. He found neither non-clinical nor clinical studies supporting claims that 7 Herb Formula or any of its individual ingredients are effective anticancer agents or inhibit tumor formation. CCFS ¶ 187. Moreover, any relevant studies on the ingredients Burdock root, Cat's Claw, Sheep Sorrel, Slippery Elm Bark, Turkish Rhubarb Root, Siberian Ginseng, and Watercress were performed either in vitro or on animals, not on humans with cancer. CCSF ¶ 188.

iii. Respondents' Claims that GDU Eliminates Tumors and Effectively Treats Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that GDU eliminates tumors and is effective in the treatment of cancer in humans. CCSF ¶ 189. He found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. CCSF ¶ 190.

However, Dr. Miller did note that curcumin (tumeric), one of GDU's ingredients, is currently being evaluated in controlled clinical trials to determine its potential as a chemoprotective and cancer preventive agent. CCSF ¶ 191. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. CCSF ¶ 192. Nevertheless, he cautioned that some studies have suggested that curcumin may actually inhibit the anticancer activity of some approved anticancer agents as well as exacerbate iron deficiency. CCSF ¶ 193. Thus, Dr. Miller advised that further research on curcumin was necessary. CCSF ¶ 194.

iv. Respondents' Claims that BioMixx Effectively Treats Cancer and Heals the Destructive Effects of Radiation and Chemotherapy Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer and heals the destructive effects of radiation and chemotherapy. CCSF ¶ 195. According to Dr. Miller, there are no reported studies of goldenseal in cancer patients. CCSF ¶ 196. BioMixx's other principal ingredients -- ginseng, shark cartilage, bromelain, and boron – appear in the other three DCO Products discussed above and were not supported by clinical data for cancer treatment. CCSF ¶ 196.

Dr. Miller also stated that "absolutely no data" supports the claim that BioMixx is used to heal the destructive effects of radiation and chemotherapy treatments. CCSF ¶ 197.

c. Respondents' Purported Experts Reinforce Dr. Miller's Conclusion that No Competent and Reliable Scientific Evidence Exists to Support Respondents' Claims.

Respondents offered five purported experts to support their case: James Duke, Ph.D. ("Duke"), Jim Dews ("Dews"), Sally LaMont ("LaMont"), Jay Lehr ("Lehr"), and Rustum Roy, Ph.D. ("Roy"). Respondents' purported experts, none of whom is a medical doctor or cancer specialist, failed to provide any evidence to controvert Dr. Miller's conclusions. CCSF ¶¶ 199, 251, 253, 263, 267, 271, 280, 289, 294, 310, 340-41, 347, 354, 358. Respondents' experts did not provide any evidence controverting Dr. Miller's conclusion that Respondents do not possess any competent and reliable scientific evidence to substantiate the representations at issue in the Complaint.

In fact, Respondents' experts reports and deposition testimony even reinforce Dr.

Miller's conclusions regarding what constitutes competent and reliable scientific evidence as well as the absence of any competent and reliable scientific evidence to support Respondents' representations. For example, consistent with Dr. Miller's view on the need for controlled clinical studies, Duke stated that "as a matter of science," he did not believe that the herbal extract working in vitro proves that it would work in a human, as Duke recognizes the difference between something being efficacious in an in vitro study and something being efficacious in humans. CCSF ¶¶ 230-31. Duke also testified that anecdotal reports were "even below . . . [his] lines of evidence." CCSF ¶ 239. LaMont testified that until there are clinical trials, "we don't know" whether DCO's products would be effective in battling cancer, and that traditional use evidence does not replace human clinical trials. CCSF ¶¶ 355 and 358. Similarly, Dews, offered as an expert in "[h]erbal formulations, specifically 7 Herb Formula," stated that animal studies could not be extrapolated to humans. CCSF ¶¶ 252 and 258.

Moreover, three of Respondents' five purported experts -- Dews, Lehr, and Roy -- had not directly studied the DCO Products and were unfamiliar with the cancer claims that Respondents have made about them. Dews testified that he was not prepared to talk about how the herbs in 7 Herb Formula may or may not benefit a person with cancer. CCSF ¶ 401. He also stated that he did not know of any studies regarding the effectiveness of 7 Herb Formula in treating, curing, or preventing cancer, or inhibiting tumor formation. CCSF ¶¶ 402-04, and 406. Furthermore, he was not familiar with any studies finding anticancer activity in any of the components of 7 Herb Formula. CCSF ¶¶ 405, and 407-13.

Lehr declined to speculate on whether Respondents' products could cure cancer because it was "outside [his] area of expertise." CCSF ¶ 280. He did not have any familiarity with Respondents' products sold to help people in the treatment of cancer, stating that his interests in

Respondents' products have "strictly been athletic," and that he "[could] only substantiate the claims that [Respondents] have made on the three products [Endurosine, Mito/ATP, and Electrocarb] that [he has] taken regularly now for ten years." CCSF ¶¶ 292 and 302. Lehr's opinion is that because these products work so well on him, Respondents' other products should be as effective. CCSF ¶ 296. However, he has not conducted any studies on the DCO Products. CCSF ¶ 289.

Respondents offered Roy as "an expert in the conduct of scientific research and with the focus on health and materials." CCSF ¶ 259. Roy and his laboratory do "zero clinical trials" and "have nothing to do with causing healing or not in a human being." CCSF ¶¶ 265-66. Roy has never done any experiments to measure the efficacy of any medical treatments "at the human level," and has not measured the efficacy of the DCO Products. CCSF ¶¶ 267-68. He testified that he "had no idea" what the DCO Products contain, and had not done any literature searches or research concerning any of the ingredients in the DCO Products. CCSF ¶¶ 269-70.

Respondents' two remaining experts, Duke and LaMont, who did indeed review the DCO Products' ingredients, echoed Dr. Miller's conclusions. Duke, who stated that he made no effort to see whether there were any studies of any sort regarding the DCO Products, testified that he would not recommend that people self-medicate with herbal remedies in treating cancer, and that he was sure there was a risk some people will pursue herbal medications instead of effective pharmaceutical medications and thereby die. CCSF ¶¶ 204-05, and 251. Duke reviewed the literature and information regarding Respondents' products and found no evidence that those products, or their ingredients, had been shown in clinical trials to be effective in the treatment of cancer. CCSF ¶¶ 370, 389-94, and 437-39. Indeed, to the contrary, Duke stated that the studies he had reviewed on the principal ingredients in two of Respondents' products – shark cartilage

(Bio*Shark) and essaic tea (7 Herb Formula) – questioned their efficiacy in treating cancer. CCSF ¶¶ 370 and 386.

LaMont stated that "cancer must be treated with conventional therapies." CCSF ¶ 322. LaMont testified that if in the course of doing a work-up on a patient, she finds "a diagnosis that looks like it could be cancer," she absolutely would refer the patient to a traditional physician and would co-manage that patient's care with the physician. CCSF ¶¶ 314, 321, and 324. She thinks that it is "best that people follow the recommendations of their oncologist and utilize protocols that are proven to be most effective for their cancer and that they should be well-informed of the potential value of the array of other therapies." CCSF ¶ 344. She added that "[t]he awareness of the powerful chemoprotective effects of plant foods and medicines should not influence patients with cancer and other serious disease to abandon using the most effective methods that modern medicine has to offer." CCSF ¶ 346.

LaMont also testified that there have been no clinical studies performed on the DCO Products, and stated that these products "are not silver bullets." CCSF ¶¶ 341- 42. LaMont acknowledged that since the DCO products have not been tested, we do not know the effectiveness of GDU, BioMixx, Bio*Shark, and 7 Herb Formula in the prevention, treatment, or cure of cancer. CCSF ¶ 340. LaMont, "[do[es]n't think that 7 Herb Formula is going to cure cancer." CCSF ¶ 419. She also testified that "[i]t would be a stretch to suggest that [the 7 Herb Formula] is on its own going to be effective in treating cancer" and that "[i]t would be a stretch for [her] that [7 Herb Formula] is a solution to cancer." CCSF ¶¶ 423 and 425. She would have a concern if 7 Herb Formula was advertised as a cancer solution. CCSF ¶ 427.

C. Respondents' Advertising Representations That the DCO Products Prevent, Treat, or Cure Cancer Are Material.

"A 'material' misrepresentation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of or conduct regarding a product. Proof of actual consumer injury is not required." *Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, *38 (1991). Courts have interpreted the *FTC Deception Policy Statement* to "presume[] materiality for express claims and claims that significantly involve health, safety, or other issues that would concern reasonable consumer[s]." *QT, Inc.*, 448 F. Supp. 2d, at 965-66 (citing *Kraft, Inc.*, 970 F.2d at 322); *see also FTC v. Cliffdale Assocs.*, 103 F.T.C. at 176-84 (1984) (claims involving "health, safety, or other areas with which the reasonable consumer would be concerned, [such as] . . . the purpose, safety, efficacy, or cost of the product . . . [or] its durability, performance, warranties or quality" are material as a matter of law). In addition, even implied claims that are "so unambiguous and repetitive that they were clearly intended by the advertiser to make the alleged claims . . . can be presumed material." *FTC v. Bronson Partners*, 564 F. Supp. 2d at 135-36.

In this case, Respondents' serious health claims were both express and so strongly implied as to be virtually express that they should be presumed material. Moreover, Respondents' claims are material because they contain information concerning the purpose, efficacy, and performance of the DCO Products that would likely affect a consumer's choice to purchase these products.

VI. COMPLAINT COUNSEL IS ENTITLED TO THE PROPOSED ORDER AGAINST RESPONDENTS.

A. James Feijo is Individually Liable and Thus An Order is Appropriate Against Him.

An individual may be held liable under the FTC Act for the violations of his corporation when the individual either participated directly in or had the authority to control the deceptive acts or practices. *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Authority to control can be established by an individual's "active involvement in business affairs and the making of corporate policy, including assuming the duties of a corporate officer." *Id.* "An individual's status as a corporate officer gives rise to a presumption of ability to control a small, closely-held corporation. 'A heavy burden of exculpation rests on the chief executive and shareholder of a closely-held corporation whose stock-in-trade is overreaching and deception.'" *Windward Marketing*, 1997 U.S. Dist. LEXIS 17114, at *38 (quoting *Standard Educ., Inc. v. FTC*, 475 F.2d 401, 403 (D.C. Cir. 1973)). As set forth herein, James Feijo both participated directly in and had the authority to control the deceptive representations. CCSF ¶¶ 2, 95, 109, 143.

B. The Proposed Order is Appropriate for Respondents' Violations.

The Commission has dealt numerous times before with cancer claims for products containing various ingredients appearing in the DCO Products and these cases resulted in consent orders with requirements similar to those in the proposed order Complaint Counsel seeks here. *In re Native Essence Herb Co.*, No. 9328 (F.T.C. Jan. 29, 2009) (order withdrawing matter from adjudication for the purpose of considering a proposed consent agreement) (cat's claw); *FTC v. Westberry Enter., Inc.*, 2008 F.T.C. LEXIS 99 (F.T.C. Sept. 18, 2008) (essiac); *In re Jenks*, 2008 F.T.C. LEXIS 94 (F.T.C. Sept. 18, 2008) (essiac); *FTC v. Natural Solution, Inc.*, No.

CV 06-06112-JFW (JTLx) (C.D. Cal. Sept. 4, 2007) (judgment and permanent injunction) (echinacea); *See, e.g., In re ForMor Inc.*, 132 F.T.C. 72 (2001) (shark cartilage); *In re Forrest*, 132 F.T.C. 229 (2001) (echinacea); *In re Miller*, 2000 F.T.C. LEXIS 70 (F.T.C. May 16, 2000) (essiac); *In re Body Systems Tech., Inc.*, 128 F.T.C. 299 (1999) (shark cartilage and cat's claw); *In re Nutrivida, Inc.*, 126 F.T.C. 339 (1998) (shark cartilage); *In re Am. Life Nutrition, Inc.*, 113 F.T.C. 906 (1990) (bee pollen).

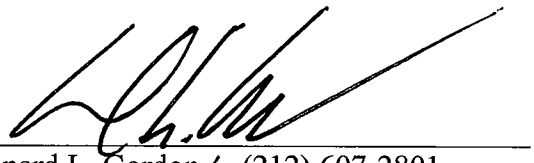
Therefore, Complaint Counsel respectfully request that the Court enter the accompanying proposed order. The proposed order prohibits Respondents from making the types of misrepresentations challenged in the Complaint and provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting future claims about the health benefits, performance, safety, or efficacy of any dietary supplement, food, drug, or other health-related product, service, or program. Finally, the undisputed facts and the law warrant the relief sought here. *See Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006) ("Congress has given the FTC primary responsibility for devising orders to address... deceptive practices, and the FTC has broad discretion to do so"); *FTC v. Colgate-Palmolive,* 380 U.S. 374, 395 (1965) ("reasonable for the [FTC] to frame its order broadly enough to prevent respondents from engaging in similar illegal practices in future advertisements"). Finally, the proposed order also contains standard provisions regarding record-keeping, dissemination of the order to officers and employees, prior notification of corporate changes, filing compliance reports, and sunsetting of the Order.

VII. CONCLUSION

Rule 3.24(a)(2) states that a party is entitled to summary decision "if the pleadings and any depositions, answers to interrogatories, admissions on file, and affidavits show that there is

no genuine issue as to any material fact and that the moving party is entitled to such decision as a matter of law." The uncontroverted evidence clearly shows that Respondents have violated Sections 5 and 12 of the FTC Act through their dissemination of unsubstantiated claims that the DCO Products prevent, treat, or cure cancer or tumors. Accordingly, Complaint Counsel respectfully request that this Court grant summary decision against Respondents.

Respectfully submitted,



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Elizabeth K. Nach (202) 326-2611

Federal Trade Commission
Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
New York, NY 10004

Dated: February 24, 2009

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 24, 2009, I have filed and served the attached **COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION, COMPLAINT COUNSEL'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY DECISION,** and **[Proposed] ORDER GRANTING COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION** upon the following as set forth below:

The original and one paper copy via overnight delivery and one electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580
E-mail: secretary@ftc.gov

Two paper copies via overnight delivery to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580

One electronic copy via email and one paper copy via overnight delivery to:

James S. Turner, Esq.
Betsy Lehrfeld, Esq.
Martin Yerick, Esq.
Swankin & Turner
1400 16th St., N.W., Suite 101
Washington, D.C. 20036
jim@swankin-turner.com

One electronic copy via email to:

Michael McCormack, Esq.
M.mccormack@mac.com

David W. Dulabon
Complaint Counsel

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
	)	
DANIEL CHAPTER ONE,	)	
a corporation, and	)	**Docket No. 9329**
	)	
JAMES FEIJO,	)	**Public Document**
individually, and as an officer of	)	
Daniel Chapter One	)	
	)	

[Proposed] ORDER GRANTING COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

Having considered Complaint Counsel's Memorandum in Support of its Motion for Summary Decision and the Statement of Material Facts as to Which There is No Genuine Issue, and Respondents' opposition thereto,

IT IS HEREBY ORDERED that Complaint Counsel's Motion for Summary Decision, filed on February 24, 2009, is **GRANTED** consistent with the Proposed Order annexed hereto.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated:

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
DANIEL CHAPTER ONE,	)	
a corporation, and	)	**Docket No. 9329**
JAMES FEIJO,	)	**Public Document**
individually, and as an officer of	)	
Daniel Chapter One	)	

[Proposed] FINAL ORDER

For purposes of this order the following definitions apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, Bio*Shark, 7 Herb Formula, GDU, and BioMixx.

3. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

4. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book

insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

5. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

6. "Commerce" shall mean as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

7. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

I.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bio*Shark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

1. Bio*Shark inhibits tumor growth;

2. Bio*Shark is effective in the treatment of cancer;

3. 7 Herb Formula is effective in the treatment or cure of cancer;

4. 7 Herb Formula inhibits tumor formation;

5. GDU eliminates tumors;

6. GDU is effective in the treatment of cancer;

7. BioMixx is effective in the treatment of cancer; or

8. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IV.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part IV.A. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any respondent, at any time prior to the issuance of this order, in connection with the purchase of Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however,* that respondents may disclose such identifying information to the FTC pursuant to Part IV.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

V.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director,

Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however**, that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may

require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

IT IS FURTHER ORDERED that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; **provided, however,** that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a Respondent in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ATTACHMENT A

LETTER TO BE SENT BY FIRST CLASS MAILã

[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought **[name of products]** from our website **[name of website]**. We are writing to tell you that the Federal Trade Commission ("FTC") has found that our advertising claims for these products were false or unsubstantiated, and has issued an Order prohibiting us from making those claims in the future. The Order entered against us also requires that we send you the following information about the scientific evidence on these products.

Very little scientific research has been done concerning Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric, Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng as a means of prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that any of these ingredients, which are included in Bio*Shark, 7 Herb Formula, GDU, and BioMixx, are effective when used for prevention or treatment for cancer in humans.

It is very important that you talk to your doctor or health care provider before using **any** alternative or herbal product, including Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric, Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric, Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancertopics/pdq; or

2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov.

You may also contact the National Cancer Institute's Cancer Information Service at 1-800-4- CANCER or 1-800-422-6237.

Sincerely,

ATTACHMENT B

Daniel Chapter One

1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated: