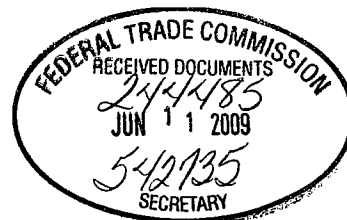


ORIGINAL



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

In the Matter of
DANIEL CHAPTER ONE,
a corporation, and

JAMES FEIJO,
individually, and as an officer of
Daniel Chapter One.

DOCKET NO. 9329

PUBLIC DOCUMENT

RESPONDENTS' REPLY TO COMPLAINT COUNSEL'S
PROPOSED FINDINGS OF FACT
AND BRIEF IN SUPPORT THEREOF

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I. RESPONDENTS' RESPONSES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

A. Daniel Chapter One and the Feijos

[Note: For Respondents' responses to Complaint Counsel's proposed findings of fact, the response of "Respondents concur" indicates that Respondents agree that Complaint Counsel's proposed finding is an accurate factual statement. The response that "Respondents have no specific response" indicates that Respondents do not believe that such proposed finding, whether or not true and/or accurate, is relevant to a material fact.]

1. Respondent Daniel Chapter One ("DCO") is a corporation sole organized in 2002 under the laws of the state of Washington. (Respondents' Answer to FTC's Compl., dated Oct. 14, 2008 (hereinafter referred to as the Answer) ¶ 1; Complaint Counsel's Trial Exhibit (hereinafter referred to as CX __) 35; J. Feijo, Hearing on Jurisdiction Transcript, April 21, 2009, (hereinafter referred to as HOJ Tr. __) at 84).

Response to Finding No. 1

Respondents concur but note that CX 35 is the Articles of Incorporation for

Messiah Y'Shua Shalom, and not for DCO.

2. According to its Articles of Incorporation, Respondent DCO's mailing and principal location is 21916 Southeast 392nd Street, Enumclaw, Washington, but neither Respondent DCO nor Respondent James Feijo maintains a building at that address. (CX 31; J. Feijo, HOJ Tr. 93-94).

Response to Finding No. 2

Exhibit CX 31 was filed with the Secretary of State for the State of Washington in 2002. The address cited is that of DCO's registered agent in Washington (HOJ, Feijo, J., Tr. 95). DCO's notice of Corporation Sole status states that Respondent James Feijo's mailing address and principle location are non-domestic (CX 31 at FTC-DCO 0739), and that Patricia Feijo's mailing address is non-domestic (CX 31 at FTC-DCO 0740).

3. According to Respondents, their principal office and place of business is located at 1028 East Main Road, Portsmouth, Rhode Island 02871. (Answer ¶ 1; Deposition of James D. Feijo, January 13, 2009, (hereinafter referred to as R15 (J. Feijo, Dep. ___)) at 99).

Response to Finding No. 3

Respondents concur but note that Respondent James Feijo practices his ministry at not just one, but many, locations (R 15 (Feijo, J., Dep. at 70, 218-19); R 16 (Feijo, P., Dep. at 38-39); HOJ, Feijo, J., Tr. 94, 96, 204; HOJ, Feijo, P., Tr. 262-64, 277).

4. Respondent James Feijo is responsible for the activities of Respondent DCO as its Overseer. (Answer ¶ 2; J. Feijo, HOJ Tr. 70; J. Feijo, Trial Transcript (hereinafter referred to as Tr. ___) at 416).

Response to Finding No. 4

Respondents concur.

5. Patricia Feijo, Respondent James Feijo's wife, is the secretary for DCO. (Deposition of

Patricia Feijo, January 14, 2009, (hereinafter referred to as (R16 (P. Feijo, Dep. at __) at 10, 52; P. Feijo, HOJ Tr. 276).

Response to Finding No. 5

Respondents concur.

6. Respondent James Feijo and his wife, Patricia, originally started DCO as a health food store in 1986. (R16 (P. Feijo, Dep. at 39-40); J. Feijo, Tr. 418).

Response to Finding No. 6

DCO did not begin as a health food store. DCO began as a ministry in 1983 (R 16 (Feijo, P., Dep. at 204-05); HOJ, Feijo, J., Tr. 182). DCO was first a street ministry and then was also a ministry to help home churches in communist countries (where church activities conducted in Christian practitioners' homes were discouraged, if not illegal) (R 15 (Feijo, J., Dep. at 73); HOJ, Feijo, J., Tr. 99, 182-83, 236-37).

7. Respondent James Feijo sold DCO products prior to registering as a corporation sole. (R15 (J. Feijo, Dep. at 224)).

Response to Finding No. 7

Respondents concur.

8. Respondents offer 150 to 200 products today, including Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "DCO Products"). (R15 (J. Feijo, Dep. at 37); P. Feijo, Tr. 392; Marino, HOJ Tr. 54; J. Feijo, HOJ Tr. 314-15).

Response to Finding No. 8

Respondents concur.

9. DCO has two buildings in Rhode Island – one is the Order Center and the other is the warehouse. (J. Feijo, HOJ Tr. 110).

Response to Finding No. 9

Respondent DCO uses, but does not own, two buildings in Rhode Island (R 15 (Feijo, J., Dep. at 72-73)).

10. Messiah Y'Shua Shalom, a Washington corporation sole, owns the property that Respondents use in Rhode Island. (R15 (J. Feijo, Dep. at 72-73); CX 35).

Response to Finding No. 10

Messiah Y'Shua Shalom owns one of the two buildings used by DCO in Rhode Island (R 15 (Feijo, J., Dep. at 72)). The other is rented from an owner unrelated to Respondents (R 15 (Feijo, J., Dep. at 174)).

11. Respondent James Feijo is the overseer for Messiah Y'Shua Shalom. (R15 (J. Feijo, Dep. at 72-73); CX 35).

Response to Finding No. 11

Respondents concur.

12. Respondents practice a science they call BioMolecular Nutrition. (CX 21).

Response to Finding No. 12

Respondent James Feijo created a combined spiritual and scientific approach to maintain the balance of bodily systems that he named BioMolecular Nutrition.

13. According to Respondents, "[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical." (CX 21).

Response to Finding No. 13

Respondents concur.

14. “The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists.” (CX 21).

Response to Finding No. 14

Respondents concur.

15. According to Respondents, “[b]ecause of BioMolecular nutritional products developed at that time, we’ve been able to support other naturopathic disciplines – chiropractic, acupuncture, herbology, and homeopathy – and using the principles of BioMolecular Nutrition has allowed many natural health practitioners to be complete.” (CX 21).

Response to Finding No. 15

Respondents concur that they made this statement.

- B. **The FTC Has Jurisdiction Over Respondent DCO, which is a Corporation within the Meaning of Section 4 of the FTC Act, and Respondent James Feijo**

Respondents’ Response:

The FTC Lacks Jurisdiction Over Respondent DCO, which is a Non-Profit,

Charitable, Religious Corporation Sole and Not a

Corporation Within the Meaning of Section 4 of the FTC Act, and Over

Respondent James Feijo, the Overseer of Daniel Chapter One

16. Respondent DCO was previously incorporated as “Daniel Chapter One, Inc.,” a Rhode Island for-profit corporation, on October 30, 1990. (CX 50; J. Feijo, HOJ Tr. 101).

Response to Finding No. 16

Between 1990 and 1997, annual for-profit corporation reports, of which Overseer

Feijo has only a vague recollection, were filed on behalf of a corporation with the

name Daniel Chapter One, Inc. with the State of Rhode Island. During that time, Daniel Chapter One, Inc.'s corporate status was repeatedly revoked, and for significant periods of time between 1991 and 1997, Daniel Chapter One, Inc. was not recognized by Rhode Island as a corporation in good standing. Respondent James Feijo never intended for DCO to be a for-profit corporation. The Challenged Products were created after Daniel Chapter One, Inc.'s corporate status was revoked (HOJ, Feijo, J., Tr. 124-25).

17. Respondent DCO's Articles of Incorporation from 1990 state that the purposes for which Daniel Chapter One, Inc. was organized were: "To engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." (CX 50; J. Feijo, HOJ Tr. 101-02).

Response to Finding No. 17

See Response to Finding No. 16. Also, the documents constituting CX 50 do not accurately reflect the manner in which Respondent DCO was conducting its activities. Instead of acting as a business engaged in the "sale, retail, wholesale, and distribution of health products," DCO was in fact a house ministry, a home church, and a home fellowship. These ministry activities were based on biblical principles and were designed to fulfill the spiritual needs of the ministry's constituents. These activities included: holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, and making healings (HOJ, Feijo, J., Tr. 180-82). Eric Chappell, a lawyer and designated local agent named in DCO's Articles of Incorporation in Rhode Island, may have

prepared the corporate documents (HOJ, Feijo, J., Tr. 200). James Feijo never intended to incorporate DCO as a for-profit corporation (HOJ, Feijo, J., Tr. 200-202). DCO frequently gave away its products free of charge (R 15 (Feijo, J., Dep. at 210-11); HOJ, Feijo, J., Tr. 137, 184; HOJ, Feijo, P., Tr. 274). DCO makes no profit from any of its activities (R 15 (Feijo, J., Dep. at 40-43, 67, 165, 191, 193, 196, 209-10, 236); R 16 (Feijo, P., Dep. at 50-51); HOJ, Feijo, J., Tr. 313, 316), including providing information through print or through its website, or from its radio show (HOJ, Feijo, J., Tr. 188).

18. Consistent with its status as a for-profit corporation incorporated in Rhode Island, Respondent DCO filed annual reports from 1991 through 1997, during which time the stated character of the business remained substantially similar, namely “To engage in the sale, retail, wholesale and distribution of health products, including health foods and supplements.” (CX 50; J. Feijo, HOJ Tr. 102-08).

Response to Finding No. 18

Respondents deny that DCO was ever a for-profit corporation and that it ever made a profit, and note that if DCO was ever a for-profit corporation, it ceased being one after its standing in Rhode Island was revoked (CX 50). Respondents also note that James Feijo has no recollection of how DCO was organized under the Rhode Island articles of incorporation, or of filing any annual reports (HOJ, Feijo, J., Tr. 107, 120-24).

19. Each of these for-profit corporation annual reports bears the signature of Respondent James Feijo. (J. Feijo, HOJ Tr. 102-08).

Response to Finding No. 19

Respondents concur that the signatures appear to belong to Respondent James Feijo's, but note that James Feijo does not recall ever having signed the documents (HOJ, Feijo, J., Tr. 106, 197).

20. DCO is not registered with the Internal Revenue Service as a charity. (R15 (J. Feijo, Dep. at 45); J. Feijo, HOJ Tr. 209).

Response to Finding No. 20

DCO has always been a religious ministry, and later became a corporation sole (HOJ, Feijo, J., Tr. 236-38). Churches, religious orders, and religious corporation soles are not required to register with the IRS. 26 U.S.C. § 501(c)(3)).

1. Respondents Are Engaged in Commerce

21. Respondents distribute the DCO Products in commerce. (Answer ¶ 4; R15 (J. Feijo, Dep. at 102); Marino, HOJ Tr. 53-55; Harrison, Tr. 295-96).

Response to Finding No. 21

Respondents do not distribute DCO products in commerce. Respondents frequently give away DCO products free of charge, works through churches or church related organizations or through members of its fellowship (R 15 (Feijo, J., Dep. at 209-11); R 16 (Feijo, P., Dep. at 69); HOJ, Feijo, J., Tr. 137, 184-88; HOJ, Feijo, P., Tr. 274; HOJ, Mink, Tr. 293-94; HOJ, Hicks, Tr. 306-07).

22. Anyone can buy and use DCO products, including people who do not believe in God. (Marino, HOJ Tr. 55; P. Feijo, Tr. 410-11).

Response to Finding No. 22

Any interested person may *obtain* DCO products (Feijo, P., Tr. 410-11).

Respondents' goal is to reach out to followers of its ministry or any other interested persons to inform them about Respondents' perspectives on the integration of spiritual and physical well-being (Feijo, P., Tr. 325-26).

23. Respondent DCO has an 800 number and a call center for consumers to purchase the DCO Products. (R16 (P. Feijo, Dep. at 67); J. Feijo, HOJ Tr. 212; P. Feijo, HOJ Tr. 273-74; J. Feijo, HOJ Tr. 168, 204, 211-12).

Response to Finding No. 23

Respondent DCO has a toll-free telephone number that enables followers of its ministry to obtain dietary supplements and discuss their physical and spiritual well-being and order dietary supplements to support their well-being (Feijo, P., Tr. 357-58).

24. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order the DCO Products. (CX 39).

Response to Finding No. 24

Respondent James Feijo created, managed, and maintained the toll-free telephone number so that followers of his ministry and other interested persons may call and discuss their physical and spiritual well-being and order dietary supplements in support of their well-being (Feijo, P., Tr. 357-58).

25. On the front page of their BioMolecular Nutrition Product Catalog, Respondents inform consumers to "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." (CX 17).

Response to Finding No. 25

Respondents have no specific response.

26. Respondents operate the Web site www.danielchapterone.com. (Answer ¶ 5; R15 (J. Feijo, Dep. at 62)).

Response to Finding No. 26

Respondents concur.

27. DCO also operates the Web sites dclpages.com and dclstore.com. (R15 (J. Feijo, Dep. at 232-33)).

Response to Finding No. 27

Respondents concur.

28. Respondents advertise their products on the Internet through the BioGuide, the Cancer Newsletter, and The Most Simple Guide to the Most Difficult Diseases, each of which is available to read or download from the Internet. (CX 1; CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55; Tr. at 264).

Response to Finding No. 28

Respondents do not advertise DCO dietary supplements. Evidence shows that most of the viewers and users of DCO's website are followers of DCO's ministry who visit DCO's website to obtain more information about DCO's products (R 15 (Feijo, J., Dep. 151-152)). Respondent DCO has no advertising budget (Feijo, J., Tr. 459, 464). Respondents do not advertise for their products through the BioGuide, the Cancer Newsletter, or the Most Simple Guide. The BioGuide was intended for sharing the Feijos' own religious testimony, and quotes verses from the Bible (R 16 (Feijo, P., Dep. at 117); Feijo, J., Tr. 452-53). The Cancer Newsletter, a one-time brochure reprinted once with minor updates, was intended for sharing testimony from users of DCO's products (Feijo, J., Tr. 452). The Most

Simple Guide was originally created for doctors at those doctors' request for information on the DCO products that people have found to be helpful (Feijo, J., Tr. 453-54).

29. Consumers learn of DCO's 800 number from the DCO Web site, the BioGuide, and Respondents' radio program, "Daniel Chapter One Health Watch." (P. Feijo, HOJ Tr. 273-74; CX 21; CX 29 (FTC-DCO 0451)).

Response to Finding No. 29

DCO's website, BioGuide, and Respondents' radio show are intended to provide information about Respondents' perspectives on spiritual and physical well-being, and do not promote DCO's products (CX 2, CX 21, CX 5). DCO's website enables the followers of Respondents' ministry to obtain DCO's products, and such followers would understand that the money they send in is a donation in support of the ministry (R 15 (Feijo, J., Dep. 151-152)). The BioGuide was intended for sharing the Feijos' own religious testimony, and quotes verses from the Bible (R 16 (Feijo, P., Dep. at 117); Feijo, J., Tr. 452-53). The radio show enables followers of Respondents' ministry to discuss their physical and spiritual well-being and to learn about non-drug approaches to balancing the body, mind, and spirit, including the use of dietary supplements to support their well-being, and does not promote DCO's products (R 15 (Feijo, J., Dep. at 238-39); R 16 (Feijo, P., Dep. at 92-93, 95); HOJ, Feijo, J., Tr. 221-24; HOJ, Feijo, P., Tr. 272-74).

30. The "Daniel Chapter One Health Watch" radio program is broadcast on the "Accent

Radio Network,” a subsidiary of Respondent DCO. (CX 32; R15 (J. Feijo, Dep. at 235).

Response to Finding No. 30

Accent Radio Network is not a subsidiary of Respondent Daniel Chapter One, and Respondents note the lack of documentary evidence to that effect (HOJ, Feijo, J., Tr. 112, 202-03; HOJ, Harrison, Tr. 246).

31. The Accent Radio Network Web site states, “Put your money where our mouth is: Accent Radio Network! We can do it for you whether you’re in a small local market or you want to hit the big time.” (CX 32). The Web site also contains an advertising schedule, which lists Accent Radio Network’s advertising rates. (CX 32; J. Feijo, HOJ Tr. 112).

Response to Finding No. 31

CX 32 does not support this proposed finding. Respondents’ copy of CX 32 consists only of page FTC-DCO 0498, and includes only introductory information about Accent Radio Network. Any revenue that Accent Radio Network receives from selling advertising time is insufficient to even support itself (R 15 (Feijo, J., Dep. at 236-37)). DCO maintains no program to sell radio advertising, has sold no such advertising, and actually pays to use the time it obtains on broadcasting networks (R 16 (Feijo, P., Dep. at 104)).

32. Respondent James Feijo’s daughter, Jill Feijo, has supervised Respondent DCO’s Order Center for the past nine years and has taken telephone orders. (CX 39; J. Feijo, HOJ Tr. 204).

Response to Finding No. 32

Respondents have no specific response.

33. DCO also accepts consumers’ orders on the Internet. (P. Feijo, Tr. 397; Marino, HOJ Tr. 54).

Response to Finding No. 33

The evidence shows that it is the followers of DCO's ministry, and not "consumers," who obtain DCO's dietary supplements via the internet (Feijo, J., Dep. 151-152).

34. DCO's Web site contains a tab inviting consumers to shop at DCO's "On-Line Store." (CX 12-15, 43).

Response to Finding No. 34

The evidence shows that (1) it is the followers of DCO's ministry, not "consumers," who obtain DCO's dietary supplements via the internet; (2) such persons likely hear about the website through DCO's radio show; and (3) such persons would understand that any money they send constitutes a donation in support of the ministry (R 15 (Feijo, J., Dep. 151-152)).

35. DCO's Web site contains an icon inviting consumers to "Buy Now." (CX 12; CX 12A; CX 13; CX 13A; CX 14; CX 14A; CX 15; CX 43; J. Feijo, HOJ Tr. 144).

Response to Finding No. 35

CX 15 and CX 43 do not support this finding. Furthermore, the pages on the dc1store.com website are from a "canned," or pre-designed, computer program.

Respondent James Feijo would like to change certain terms used in that program, but it is expensive to hire someone to do so (R 15 (Feijo, J., Dep. at 149-152)). In addition, the "Buy Now" icon appears only inconspicuously on the side of the webpage constituting CX 12; the icon appears only once in the entire 15 pages constituting CX 13; and CX 14 has no such icon, but rather only two very

inconspicuous links in fine print on the side of one page.

36. Respondents' acquisition costs for the products they sell is 30 percent of the price Respondents charge to consumers for products such as 7 Herb Formula. (R15 (J. Feijo, Dep. at 232)).

Response to Finding No. 36

The above-mentioned 30 percent constitutes only the cost of production (R 15 (Feijo., J, Dep. at 232)). There are many other costs involved, and DCO makes no net profit from its products (R 15 (Feijo, J., Dep. at 40, 42-43, 165); R 16 (Feijo, P., Dep. at 65); HOJ, Feijo, J., Tr. 313, 316). Also, Respondents do not "charge" "consumers" for DCO's products. The price is a suggested donation amount from the followers of DCO's ministry and other interested persons (R 15 (Feijo, J., Dep. at 146-147, 210-12)). The suggested donation amount is fair and reflects the extrinsic value of the products (HOJ, Mink, Tr. 286-89). In addition, DCO has a program that provides products at free or reduced prices to individuals whose ministry vouches for them (HOJ, Mink, Tr. 283-86).

37. Over a thousand consumers have purchased DCO's products. (R16 (P. Feijo, Dep. at 57)).

Response to Finding No. 37

There is no evidence that "over a thousand consumers have purchased" DCO's products. Patricia Feijo stated that she does not know the number of people who have obtained DCO's products (R16 (P. Feijo, Dep. at 57)). Furthermore, "consumers" do not "purchase" DCO's products. The price is a suggested

donation amount from the followers of DCO's ministry and other interested persons seeking to learn about or use agents that are alternative and complementary to pharmaceutical agents (R 15 (Feijo, J., Dep. at 146-47, 210-12)).

38. Respondents have generated approximately \$2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's two-hundred products. (CX 44; R15 (J. Feijo, Dep. at 206, 212); J. Feijo, HOJ Tr. 109, 223-24).

Response to Finding No. 38

Page 206 of James Feijo's deposition, as cited by Complaint Counsel, does not support this finding. Respondents James Feijo did testify that the total annual current contributions to the ministry are about \$1.7 million per year and that donations via the web are a small percentage of that amount (R 15 (Feijo, J., Dep. at 223-25)). Even though Respondents have provided \$1.7 million worth of DCO dietary supplements, Respondents make no net profit from their products (R 15 (Feijo, J., Dep. at 40, 42-43, 165); R 16 (Feijo, P., Dep. at 65); HOJ, Feijo, J., Tr. 313, 316). Respondents have often received no donation for its their dietary supplements, and at other times have received much less than the suggested donation amount (R 15 (Feijo, J., Dep. at 38, 146-47, 155, 209-11); R 16 (Feijo, P., Dep. at 64, 68-69); HOJ, Feijo, J., Tr. 137, 184-88, 313; HOJ, Feijo, P., Tr. 274; HOJ, Mink, Tr. 283-86, 291, 293-94; HOJ, Hicks, Tr. 306-07).

39. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed is for a donation. (R15 (J. Feijo, Dep. at 158); R16 (P. Feijo, Dep. at 76-77); J. Feijo, HOJ Tr. 140).

Response to Finding No. 39

The evidence shows that the BioMolecular Nutrition Product Catalog was printed once and likely is no longer in use (R 15, Feijo, J., Dep. at 159; R 16, Feijo, P., Dep. at 75-77). Furthermore, Patricia Feijo was not familiar with the BioMolecular Nutrition Product Catalog until it was shown to her the night before her deposition (R 16 (Feijo, P., Dep. at 75-77)). Therefore, Complaint Counsel's above citation to Patricia Feijo's deposition does not support its Proposed Finding No. 39. In addition, as a one-time publication, there is no indication that the Product Catalog is a primary, or even significant, source of information about DCO's activities.

40. There is no mention of the DCO ministry in the BioMolecular Nutrition Product Catalog. (R15 (J. Feijo, Dep. at 161)).

Response to Finding No. 40

See Response to Finding No. 39. The evidence shows that the BioMolecular Nutrition Product Catalog was printed once and is no longer in use (R 15 (Feijo, J., Dep. at 159); R 16 (Feijo, P., Dep. at 75-77)).

41. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the DCO Products from Respondents' Web site. (CX 10; Marino, HOJ Tr. 53-55, 62-67).

Response to Finding No. 41

Any evidence of the undercover "purchase" of dietary supplements through the DCO website would be a characterization given the transaction by Complaint Counsel or their investigator. Respondents have repeatedly testified that they treat all money from the website and other parts of the ministry as donations.

Investigator Marino was directed to the web site by FTC officials seeking to prosecute Respondents (R 11 (Marino, Dep. at 16-18)). There is no evidence that anyone not seeking alternative and complementary products to conventional chemotherapeutic medical treatments would seek, or even know to look for, dietary supplements from Respondents.

42. At the time of Marino's purchase, each of the DCO Products was displayed on Respondents' Web site with a picture of the product, a short description of the product, and a corresponding price. (Marino, HOJ Tr. 54).

Response to Finding No. 42

The term "price" on the DCO website is part of the "canned" software used by the ministry that is expensive and difficult to change (Feijo, J., Dep. 149-152).

43. There were no indications on Respondents' Web site that the DCO Products could be obtained in exchange for a donation, that these products could be purchased for a reduced price, or that these products could be received for free. (Marino, HOJ Tr. 54-55).

Response to Finding No. 43

Respondents do not advertise the existence of the website. The evidence shows that most of the viewers and users of the website become aware of its existence from listening to the ministry's radio programs. Those viewers/users would be aware that they are receiving agents alternative and complementary to chemotherapeutic agents and that they are making donations to the ministry (R 15 (Feijo, J., Dep. 151-152)). The availability of products for free or for a reduced donation is made known to people who indicate that they have limited resources (R 16 (Feijo, P., Dep. at 64, 68)). These people are either given free products or

may go to a church and have the minister vouch for them (R 16 (Feijo, P., Dep. at 64, 68); R 15 (Feijo, J., Dep. at 38, 146-47); HOJ, Mink, Tr. 283-86, 291).

44. Prior to making the purchase, Marino created an undercover e-mail account to confirm and monitor the progress of the purchase and received four emails from Respondents relating to the purchase of the DCO Products. (CX 33; Marino, HOJ Tr. 56-59).

Response to Finding No. 44

Respondents have no specific response.

45. One of the emails Marino received, which was sent the day after he purchased the DCO Products, stated, "We appreciate your business with us," and offered a ten percent discount on a subsequent purchase. (Marino, HOJ Tr. 59).

Response to Finding No. 45

Respondents have no specific response.

46. On or about January 24, 2008, Marino received the DCO Products. (CX 34; Marino, HOJ Tr. 60).

Response to Finding No. 46

Respondents have no specific response.

47. Included in the shipment of the DCO Products ordered by Marino were the following: (a) BioGuide 3: The BioMolecular Nutrition Guide to Natural Health 3; (b) "BioMolecular Nutrition Product Catalog;" (c) a blank purchase order form; and (d) an invoice form. (CX 34; Marino, HOJ Tr. 55-56, 61).

Response to Finding No. 47

Respondents have no specific response.

48. According to the UPS Ground shipping label attached to the package containing the DCO Products and the DCO materials, the shipment originated from Daniel Chapter One, 822 Anthony Road, Portsmouth Rhode Island 02871-5604 and was sent to an FTC undercover address in a state other than Rhode Island in the United States. (CX 34; Marino, HOJ Tr.

60).

Response to Finding No. 48

CX 34 does not support this proposed finding. Page FTC-DCO 2943 of CX 34

states at the top:

Daniel Chapter One
1028 E Main Road
P.O. Box 223
Portsmouth, RI 02871-0223

49. The shipment of the DCO Products did not contain any documents indicating that the purchase was a “donation” or thanking the purchaser for making a “donation” to Daniel Chapter One. (CX 34; Marino, HOJ Tr. 60).

Response to Finding No. 49

If ordering products through DCO’s website, a person would know before receiving the products that any money given constitutes a donation. As previously mentioned, persons who obtain DCO products through DCO’s website are aware that they are making donations to the ministry (R 15 (Feijo, J., Dep. at 151-52)). If ordering products through DCO’s call center, a person would be informed during the call that any money given for a product constitutes a donation (R 16 (Feijo, P., Dep. at 64)).

50. According to Commission records, the amount charged to the undercover credit card used for the purchase of the DCO Products was \$175.75. These records also indicate that this charged was made by “DANIEL CHAPTER ONE.” (CX 34; Marino, HOJ Tr. 58, 60).

Response to Finding No. 50

Respondents have no specific response.

51. DCO's shipping and handling fees for its products are \$20.95. (R15 (J. Feijo, Dep. at 152-53)).

Response to Finding No. 51

Respondents have no specific response.

52. DCO offers coupons to consumers for their next online store order. (R15 (J. Feijo, Dep. at 154); Marino, HOJ Tr. 59; J. Feijo, HOJ Tr. 149-50).

Response to Finding No. 52

Respondents have no specific response.

53. Respondents run promotions from time to time to "give [consumers] more of an opportunity to . . . get things at a lower rate." (R15 (J. Feijo, Dep. at 154)).

Response to Finding No. 53

Respondent James Feijo never used the word "consumers" in the sentence above.

In the sentence above, James Feijo actually used the word "people," which

Complaint Counsel replaced with the word "consumers." In using the word

"people," James Feijo was referring to the followers of his ministry and other

persons who are interested in DCO and its products (R15 (J. Feijo, Dep. at 154)).

54. For example, consumers can buy multiple bottles and get a bottle free. (R15 (J. Feijo, Dep. at 232)).

Response to Finding No. 54

See Response to Finding No. 53 regarding the use of the term "consumers." In

addition, Complaint Counsel has taken the sentence out of context. James Feijo

was proceeding to explain how interested persons are able to obtain an extra bottle

if they are in need and cannot afford to make a donation (R15 (Feijo, J., Dep. at 232)).

55. Consumers can also join DCO's Bucket-A-Month Club to obtain volume discounts on DCO's products. (CX 29 at FTC-DCO 0430; J. Feijo, HOJ Tr. 140-41).

Response to Finding No. 55

The purpose of the Bucket-A-Month Club is not to give incentives to "consumers" to buy DCO's products, but rather to make products available to followers of DCO's ministry or other interested persons who cannot afford to make a donation (HOJ, Feijo, J., Tr. 141). "Interested persons" specifically means those who share DCO's view that using agents that are alternative and complementary to pharmaceutical agents is healthier and more in line with their views of humanity, values, and spiritual and physical health ((R 16 (Feijo, P., Dep. at 80-81; Feijo, P. Tr. 337-40, 342, 349, 356-57, 404, 412-413)).

56. On their Web site dc1store.com, Respondents state: "For Information on Special offers for *purchasing* multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon-Fri." (CX 17 (emphasis added)).

Response to Finding No. 56

The pages on the dc1store.com website are from a "canned" program. Respondent James Feijo would like to change certain terms used in that program, but it is expensive to hire someone to do so (Feijo, J., Dep. at 149-152).

57. Respondents' Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, costs \$5.95. (CX 23; CX 24).

Response to Finding No. 57

Respondent DCO has never charged money for the Cancer Newsletter (Feijo, P., Tr. 387). The price, which is in small font and printed inconspicuously on the very last page, is merely the suggested value. There is no evidence that anyone has ever paid for the Cancer Newsletter (Feijo, P., Tr. 387).

58. In their Cancer Newsletter, Respondents instruct consumers to call “1-800-504-5511” to order their products. (CX 23; CX 24).

Response to Finding No. 58

Respondents’ Cancer Newsletter does not “*instruct*” consumers to call 1-800-504-5511 to order their products. Instead, the 800-number is passively listed at the bottom of the web page in a font size/style that is not inconsistent with the font used throughout the Newsletter (CX 23; CX 24). In addition, the Cancer Newsletter is not intended for “consumers.” Instead, the purpose of the Cancer Newsletter is to share testimonies and product information with Respondents’ ministry and other interested persons – persons seeking something other than chemotherapeutic agents (Feijo, P., Tr. 387).

59. In their Cancer Newsletter, Respondents state that their “[l]atest Bioguide” is “[o]nly \$9.95.” (CX 23; CX 24).

Response to Finding No. 59

Respondent DCO has never charged money for the Bioguide (Feijo, P., Tr. 389). As for all of the literature that DCO has published, the price shown is merely the suggested value (Feijo, P., Tr. 387). In addition, Complaint Counsel’s Proposed

Finding No. 60 supports the fact that Respondents do not charge money for the Cancer Newsletter, as interested persons may download the Cancer Newsletter for free.

60. The Cancer Newsletter is available online on DCO's web site. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; Tr. 264).

Response to Finding No. 60

The Cancer Newsletter may be downloaded for free from DCO's website (CX 13; [Turner], Tr. 264).

61. Respondents' publication entitled The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide costs \$12.95. (CX 20).

Response to Finding No. 61

DCO has never charged money for The Most Simple Guide (Feijo, P., Tr. 383-84). The price is merely the suggested value. In addition, Complaint Counsel's Proposed Finding No. 62 supports the fact that Respondents do not charge money for The Most Simple Guide, as interested persons may download the Guide for free (Feijo, P. Tr. 395; Feijo, J., Tr. 453-455).

62. The Most Simple Guide can be accessed by anyone online. (P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).

Response to Finding No. 62

Respondents have no specific response.

63. A number of stores nationally sell DCO's products, including stores in Georgia and a store in Pennsylvania. (R16 (P. Feijo, Dep. at 72)).

Response to Finding No. 63

Patricia Feijo was asked by Complaint Counsel how many stores *carry*, and not how many stores *sell*, DCO products. There are “not that many” stores which carry DCO’s products (R 16 (Feijo, P., Dep. at 72)). There are “a couple” of such stores in Georgia, “one or two” in Florida, and one in Pennsylvania (R 16 (Feijo, P., Dep. at 72)), all of which are similar ventures managed by individuals who share Respondents’ view of the need for the balancing of mind, body, and spirit (R 16 (Feijo, P., Dep. at 71, 73); J. Feijo, HOJ Tr. 189; HOJ, Mink, Tr. 289-90, 311-12; Harrison, Tr. 296-97).

64. Respondents use distributors in various states who carry DCO’s products. (J. Feijo, HOJ Tr. 132-35).

Response to Finding No. 64

Respondents’ “distributors” are actually followers of Respondents’ ministry or are otherwise well aware of DCO’s religious principles (R 16 (Feijo, P., Dep. at 71, 73); J. Feijo, HOJ Tr. 189; HOJ, Mink, Tr. 289-90, 311-12; Harrison, Tr. 296-97).

65. Respondents have created a brochure entitled “The Truth Will Set You Free” to convince companies to become carriers of DCO products. (CX 22; J. Feijo, HOJ Tr. 135). Among the benefits listed in the brochure are financial rewards such as “boost[ed] sales” and “earnings potential.” (CX 22; J. Feijo, HOJ Tr. 136). The brochure also states that Respondent DCO “is the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store.” (CX 22).

Response to Finding No. 65

Respondents’ brochure is not meant to convince companies to carry DCO

products. Respondents do not solicit companies to carry their products (R 16 (Feijo, P., Dep. at 71)). The stores and doctors' offices that carry DCO products have approached DCO on their own initiative, and have done so because they are part of DCO's ministry or are otherwise in support of DCO's religious message (R 16 (Feijo, P., Dep. at 71)). Furthermore, in their brochure, Respondents make clear from the initial pages that DCO's mission is religion-based and that DCO's goal is to help people attain a better quality of life. It urges readers of the brochure to "call DCO today and make a difference" (CX 22).

66. Respondent have called some distributors of DCO products "silver-line carriers" and "gold-line carriers." (J. Feijo, HOJ Tr. 125). "Gold-line carriers" maintain a broader range of products than the "silver-line carriers." (J. Feijo, HOJ Tr. 126).

Response to Finding No. 66

Respondents have no specific response.

67. Respondents' distributors have included stores such as Nature's Pharmacy in Altoona, Florida; Herb Shop Unlimited, in Adel, Georgia; The Poppyseed in Peculiar, Missouri; Herbal Connection in Lake Park, Georgia; Beehive Natural Foods in Poplar Bluff, Missouri; Discount Nutrition in Monroeville, Pennsylvania; and Organic Pride in Plant City, Florida. (J. Feijo, HOJ Tr. 131-32).

Response to Finding No. 67

See Response to Finding No. 63. Respondents have no further specific response.

68. Respondents' distributors have also included chiropractic centers. (J. Feijo, HOJ Tr. 134-35).

Response to Finding No. 68

The chiropractic centers that carry DCO products are owned by members or

supporters of the DCO ministry. Respondents have been chided in certain chiropractic magazines for refusing to allow certain doctors to continue carrying DCO products because Respondents felt that those doctors were acting inconsistently with DCO's religious principles (HOJ, Feijo, J., Tr. 130).

69. Doctors and stores that carry DCO's product line get the product at a lesser price because they are going to be selling it. (R16 (P. Feijo, Dep. at 71)).

Response to Finding No. 69

Respondents have no specific response.

70. One doctor who is a distributor places about a 40 percent markup on the DCO products he sells. (Mink, HOJ Tr. 287-88; J. Feijo, HOJ Tr. 311).

Response to Finding No. 70

The 40 percent markup, in addition to what Dr. Mink has paid for the DCO product, reflects the extrinsic value of the product (HOJ, Mink, Tr. 286-89), and is included in the figures previously cited by Complaint Counsel.

71. On their Web site dclstore.com, Respondents promote an affiliate program, stating the following: "**Welcome to the DC1 Affiliate Program!** Our program is free to join, it's easy to sign-up and requires no technical knowledge. Affiliate programs are common throughout the Internet *and offer website owners a means of profiting from their websites. Affiliates generate sales for commercial websites* and in return receive a percentage of the value of those sales. **How Does It Work?** When you join the DC1 Affiliate Program, you will be supplied with a range of banners and textual links that you place within your site. When a user clicks on one of your links to the DC1 Affiliate Program, their activity will be tracked by our affiliate software. You will earn a commission based on your commission type. **Real-Time Statistics and Reporting!** Login 24 hours a day to check your sales, traffic, account balance and see how your banners are performing. You can even test conversion performance by creating your own custom links! Affiliate Program Details. Pay-Per-Sale: 10% of all sales you deliver. \$100.00 USD - Minimum balance required Payments are made on the 1st of each month, for the previous month." (CX 29 (emphasis in bold in original; emphasis in italics supplied)).

Response to Finding No. 71

CX 29 does not support this proposed finding. Rather, CX 29 consists of pages from danielchapterone.com, with no reference to DCO's affiliate program.

Furthermore, James Feijo took no part in implementing this portion of DCO's website, and this portion is inconsistent with DCO's principles (HOJ, Feijo, J., Tr. 114-15).

72. An entity does not have to be a religious ministry to become an affiliate of Respondent DCO. (J. Feijo, HOJ Tr. 114).

Response to Finding No. 72

Although an entity does not have to be a religious ministry to affiliate with DCO, the doctors and stores who approach DCO to carry DCO's products are indeed followers of DCO's ministry (R 16 (Feijo, P., Dep. at 71)). In addition, Respondents have discontinued their relationships with doctors who acted inconsistently with DCO's religious principles, which reject commercialism (HOJ, Feijo, J., Tr. 130).

73. The trademark symbol appears next to Respondents' term "BioMolecular Nutrition" and Respondents' products 7 Herb Formula, GDU, and BioMixx. (CX 17).

Response to Finding No. 73

CX 17 does not support this finding in relation to BioMixx. Also, it is not uncommon for non-profit organizations to have trade marks, which is not necessarily an indication that such organizations engage in commerce.

74. There only has been one version of each of the DCO Products, and the information relating to the identity of each ingredient and the amount of each ingredient is contained on the labels for the DCO Products. (CX 39).

Response to Finding No. 74

There have been different versions of 7 Herb Formula (Feijo, P., Tr. 437-39).

BioShark

75. Bio*Shark is a product that contains, among other ingredients, Shark Cartilage. (Answer ¶ 6). Each Bio*Shark product 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. (Answer ¶ 6; CX 17).

Response to Finding No. 75

Respondents have no specific response.

76. Respondents offer one bottle of Bio*Shark for \$65.95 (300 of the 800 mg capsules) and \$30.95 (100 of the 800 mg capsules). (Answer ¶ 6).

Response to Finding No. 76

The amount listed is the suggested value or requested donation for the product and reflects its extrinsic value (R 15 (Feijo, J., Dep. at 146-147)).

77. Respondents pay Universal Nutrition \$3.15 per unit for the 100 capsule bottle of Bio*Shark and \$8.75 per unit for the 300 capsule bottle of Bio*Shark. (Deposition of Claudia Petra Bauhoffer-Kinney, January 15, 2009, (hereinafter referred to as R17 (Bauhoffer-Kinney, Dep. at ___)) at 44).

Response to Finding No. 77

Respondents have no specific response.

78. During 2008, Respondents paid Universal Nutrition approximately \$1,437 to manufacture

479 units of the 100 capsule bottle of Bio*Shark and approximately \$6,256 to manufacture 782 units of the 300 capsule bottle of Bio*Shark. (R17 (Bauhoffer-Kinney, Dep. at 45)).

Response to Finding No. 78

Respondents have no specific response.

79. Universal Nutrition does two things - it has its own brand of products, and it also is a private label manufacturer. (R17 (Bauhoffer-Kinney, Dep. at 17)).

Response to Finding No. 79

Respondents have no specific response.

80. DCO falls under the private label part of Universal Nutrition. (R17 (Bauhoffer-Kinney, Dep. at 17)).

Response to Finding No. 80

Respondents have no specific response.

81. Universal Nutrition makes approximately 35-40 products for DCO, including Bio*Shark, GDU, and BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 21)).

Response to Finding No. 81

Respondents have no specific response.

82. Universal Nutrition started manufacturing Bio*Shark for Respondents approximately eight to ten years ago. (R17 (Bauhoffer-Kinney, Dep. at 42-43)).

Response to Finding No. 82

Respondents have no specific response.

7 Herb Formula

83. 7 Herb Formula is a liquid tea concentrate product that contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. (Answer ¶ 8). Respondents' product label directs users to take 1-2 ounces of 7 Herb Formula with 2-4 ounces of hot or cold filtered or distilled water. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition Health care professional. (Answer ¶ 8; CX 17).

Response to Finding No. 83

Respondents have no specific response.

84. 7 Herb Formula is essiac plus watercress, Cat's Claw, and Siberian Ginseng. (P. Feijo, Tr. 439).

Response to Finding No. 84

7 Herb Formula is composed of "the four original essiac substances" plus watercress, Cat's Claw, and Siberian Ginseng (Feijo, P., Tr. 439), formulated by James Dews, a well-known, long-established herbal product formulator (R 19 (Dews, Dep. at 34-35, 56-57); Feijo, J., Tr. 441).

85. Respondents offer one 32-ounce bottle of 7 Herb Formula for \$70.95. (Answer ¶ 8).

Response to Finding No. 85

The amount listed is the suggested value or requested donation for the product (R 15 (Feijo, J., Dep. at 146-147)).

86. On their Web sites danielchapterone.com and dc1pages.com, Respondents state the following regarding 7 Herb Formula: "I think it costs too much: Essiac formulas normally retail for \$45 to \$69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! ***Daniel Chapter One's 7 Herb Formula is equally priced with most other brands but with ours you get a great deal more.*** Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is

the case you must at least double the price they are asking to get equal price comparison.” (CX 18 (emphasis added)).

Response to Finding No. 86

The amount listed is the suggested value or requested donation for the product (R 15 (Feijo, J., Dep. at 146-147)).

GDU

87. GDU is a product that contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. (Answer ¶ 10). Respondents’ GDU product 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. (Answer ¶ 10; CX 17).

Response to Finding No. 87

Respondents have no specific response.

88. Respondents offer GDU for \$45.95 (300 capsules) and \$29.95 (120 capsules). (Answer ¶ 10).

Response to Finding No. 88

The amount listed is the suggested value or requested donation for the product (R 15 (Feijo, J., Dep. at 146-147)).

89. Respondents pay Universal Nutrition \$3.28 per unit for the 120 tablet [sic] bottle of GDU and \$7.07 per unit for the 300 tablet [sic] bottle of GDU. (R17 (Bauhoffer-Kinney, Dep. at 34-35)).

Response to Finding No. 89

Respondents have no specific response.

90. During 2008, Respondents paid Universal Nutrition approximately \$5,127 to manufacture

1,709 units of the 120 tablet [sic] bottle of GDU and approximately \$52,661 to manufacture 7,523 units of the 300 tablet [sic] bottle of GDU. (R17 (Bauhoffer-Kinney, Dep. at 34-35)).

Response to Finding No. 90

Respondents have no specific response.

BioMixx

91. BioMixx is a product that contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. (Answer ¶ 12). Respondents' product label for BioMixx directs users to take five scoops daily. (Answer ¶ 12; CX 17).

Response to Finding No. 91

Respondents have no specific response.

92. Respondents offer BioMixx for \$40.95 (3 lb. powder) and \$22.95 (1 lb. powder). (Answer ¶ 12).

Response to Finding No. 92

The amount listed is the suggested value or requested donation for the product (R 15 (Feijo, J., Dep. at 146-147)).

93. Respondents pay Universal Nutrition \$11.50 per unit for the 3 pound bottle of BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 46)).

Response to Finding No. 93

Respondents have no specific response.

94. During 2008, Respondents paid Universal Nutrition approximately \$8,778 to manufacture 798 units of the 3 pound bottle of BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 46)).

Response to Finding No. 94

Respondents have no specific response.

2. Respondent James Feijo Controls Respondent DCO's Finances and Operations

95. Respondent James Feijo is ultimately in charge of Daniel Chapter One. (J. Feijo, HOJ Tr. 112).

Response to Finding No. 95

Respondent James Feijo is the overseer of Daniel Chapter One (R 1).

96. Respondent James Feijo is responsible for the development, creation, production, and pricing of the DCO Products. (CX 39; R15 (J. Feijo, Dep. at 116); R16 (P. Feijo, Dep. at 77)).

Response to Finding No. 96

Respondents concur.

97. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage of the DCO products. (CX 39).

Response to Finding No. 97

James and Patricia Feijo have created and drafted the directions for usage of the DCO products based on scientific research that they have commissioned and consulted, and also based on their own research (R 16 (Feijo, P., Dep. at 166-67, 192-93); Feijo, J., Tr. 431-33).

98. Respondent James Feijo and Patricia Feijo developed the recommended dosages of the DCO Products. (CX 39; R16 (P. Feijo, Dep. at 117, 166-67, 192)).

Response to Finding No. 98

See Response to Finding No. 97.

99. Respondent James Feijo is the trustee for all Daniel Chapter One assets, including all funds, which are to be held in trust. (CX 39; J. Feijo, HOJ Tr. 73).

Response to Finding No. 99

Respondents concur.

100. Respondent DCO has bank accounts with Citizens Bank. (CX 49).

Response to Finding No. 100

Respondents have no specific response.

101. All of the revenue earned by Respondent DCO is deposited in the DCO bank account before being distributed, at Respondent James Feijo's discretion, to other bank accounts such as a "Creation Science Funding," "Radio Leasing International," "Business Partners Checking," and "Business Partners Money Market Fund." (J. Feijo, HOJ Tr. 206-08, 227, 230).

Response to Finding No. 101

Respondents have no specific response.

102. Patricia Feijo is a signatory to DCO's bank account and writes checks on behalf of the DCO account. (R16 (P. Feijo, Dep. at 54); P. Feijo, HOJ Tr. 276).

Response to Finding No. 102

Respondents have no specific response.

103. Jill Feijo, James Feijo's daughter, pays DCO's bills. (J. Feijo, HOJ Tr. 204).

Response to Finding No. 103

Respondents have no specific response.

3. Respondents Do Not Maintain Records

104. DCO has a policy of not maintaining records. (J. Feijo, HOJ Tr. 73, 83).

Response to Finding No. 104

Respondents follow their religious principles, which do not support maintaining records (R 15 (Feijo, J., Dep. at 22-25); HOJ, Feijo, J., Tr. 74, 76, 78, 198).

105. Respondent James Feijo did not change DCO's document retention policies after learning that the FTC had brought a proceeding against him and DCO. (J. Feijo, HOJ Tr. 80).

Response to Finding No. 105

Respondent James Feijo did not know the nature of the FTC proceedings, and the proceedings did not change his religious principles. (HOJ, Feijo, J., Tr. 77, 80).

106. DCO did not change its document retention policies after receiving the Court's first and second orders to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 81-83).

Response to Finding No. 106

DCO complied with this Court's orders and provided all information requested, such as bank account numbers and financial summaries in DCO's possession.

107. Respondent James Feijo had the authority to change DCO's document retention policy after receiving the Court's orders to produce certain documents to Complaint Counsel if he thought the records would show that DCO was a nonprofit corporation. (J. Feijo, HOJ Tr. 83).

Response to Finding No. 107

Respondent James Feijo did not change DCO's document retention policy because doing so would have been inconsistent with his religious teachings/principles (R 15 (Feijo, J., Dep. at 22-25); HOJ, Feijo, J., Tr. 74, 76, 78, 198). The corporate and financial records produced show that Respondent DCO is a non-profit corporation sole (R 1, CX 49 & CX 50).

108. DCO continued to throw out documents, including Marino's purchase order form, even after receiving the Court's orders to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

Response to Finding No. 108

Respondents follow their religious principles, which do not support maintaining records (R 15 (Feijo, J., Dep. at 22-25); HOJ, Feijo, J., Tr. 74, 76, 78, 198).

4. **Respondents Profit from the Sale of the DCO Products**

Respondents' Response:

Respondents Do Not Profit from the Sale of the DCO Products

109. James and Patricia Feijo live in the Portsmouth, Rhode Island property owned by Messiah Y'Shua Shalom as well as in a three-bedroom property in Deerfield Beach, Florida, which Respondent DCO owns. (R15 (J. Feijo, Dep. at 70-71; 78-79); J. Feijo, HOJ Tr. 160, 204).

Response to Finding No. 109

Respondents do not have any fixed location as their residence (R 15 (Feijo, J., Dep. at 70); HOJ, Feijo, J., Tr. 96, 204; HOJ, Feijo, P., Tr. 277). Respondents are sometimes housed in their ministry's property because Respondents' religious

principles do not support acquiring material possessions (R 15 (Feijo, J., Dep. at 78, 224); R 16 (Feijo, P., Dep. at 55); HOJ, Feijo, P., Tr. 264). It is common for non-profit ministries to provide housing for their principals. The ministry houses have also housed many others (HOJ, Harrison, Tr. 252-53).

110. Respondent DCO owns two cars - a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. (R15 (J. Feijo, Dep. at 71); J. Feijo, HOJ Tr. 160).

Response to Finding No. 110

Respondents concur. The Fair Market Value of the 2003 Cadillac is \$7,690, and the Fair Market Value of the 2004 Cadillac is \$12,115.¹

111. Respondent James Feijo uses the two Cadillacs owned by DCO. (R15 (J. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 160).

Response to Finding No. 111

Respondents concur that James Feijo uses the cars, just as other members of the ministry also use said cars in Rhode Island and Florida, where the cars are located (R 15 (Feijo, J., Dep. at 97)). Respondents live modestly (R 15 (Feijo, J., Dep. at 79, 95-97, 217-20, 227); HOJ, Feijo, J., Tr. 183-84); HOJ, Mink, Tr. 299-300; HOJ, Harrison, Tr. 247).

112. Respondent DCO pays for all of the Feijos' living expenses. (CX 39; J. Feijo, HOJ Tr. 206; P. Feijo, HOJ Tr. 276).

Response to Finding No. 112

DCO pays for the Feijos' living expenses as is usual in the relationship between

¹ Based on Kelley Blue Book Private Party Values for a 2003 Cadillac DeVille Sedan 4D with 46,000 miles and a

overseers and religious organizations. The Feijos own no personal or real property (R 15 (Feijo, J., Dep. at 70); R 16 (Feijo, P., Dep. at 56). The Feijos have no health insurance, life insurance, IRAs, retirement funds, or personal savings, and receive no salary (R 15 (Feijo, J., Dep. at 69, 192, 227); R 16 (Feijo, P., Dep. at 54-55). The Feijos live modestly (R 15 (Feijo, J., Dep. at 79, 95-97, 217-20, 227); HOJ, Feijo, J., Tr. 183-84); HOJ, Mink, Tr. 299-300; HOJ, Harrison, Tr. 247).

113. Respondents do not maintain any records on how much DCO money is spent on the Feijos' living expenses. (P. Feijo, HOJ Tr. 277).

Response to Finding No. 113

Respondents follow their religious principles, which do not support maintaining records (R 15 (Feijo, J., Dep. at 22-25); HOJ, Feijo, J., Tr. 74, 76, 78, 198).

Complaint Counsel indeed obtained the Feijos' credit card charges from the credit card company, such records of which the Feijos do not maintain on their own.

114. The Feijos do not file any tax returns with regard to the money they receive from Respondent DCO. (P. Feijo, HOJ Tr. 278).

Response to Finding No. 114

The Feijos receive only living expenses and do not receive a salary or other income from DCO (R 15 (Feijo, J., Dep. at 192); R 16 (Feijo, P., Dep. at 54)).

Members of a religious order who have taken a vow of poverty are not required to pay self-employment tax, Federal Insurance Contributions Act (FICA) tax or federal income tax withholding for remuneration received for services performed

in the exercise of their duties. 26 U.S.C. § 1402(c)(4), 3121(b)(8)(A) and 3401(a)(9).

115. Respondent DCO pays for pool and gardening services rendered on the “Feijo house” in Florida. (CX 49 at FTC-DCO 3443, 3457).

Response to Finding No. 115

There is no “Feijo house.” The houses – one in Rhode Island and one in Florida – which Respondent James Feijo and his wife use are owned by Respondent Daniel Chapter One and Corporation Sole Messiah Y’Shua Shalom (CX 31, CX 35 and R15 Feijo, J. Dep. 70-72), and are used for a wide range of ministry activities involving numerous members of the ministry (HOJ, Harrison, Tr. 252-53). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956). All houses require maintenance.

116. Respondent DCO pays for Patricia Feijo’s tennis club membership. (P. Feijo, HOJ Tr. 278).

Response to Finding No. 116

The Feijos receive only living expenses and receive no salary or other compensation from DCO, and Patricia Feijo relies on tennis as a way to maintain her health (HOJ, Feijo, J., Tr. 155-56; HOJ, Feijo, P., Tr. 278-79). Under federal law, payment of normal living expenses of a minister and his family is not

considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

117. Respondent DCO paid for Respondent James Feijo's membership at the Green Valley Country Club in Rhode Island. (J. Feijo, HOJ Tr. 154-55).

Response to Finding No. 117

The Feijos receive only living expenses and receive no salary or other compensation from DCO, and James Feijo uses golfing as an opportunity to spread his faith and minister to interested persons (HOJ, Feijo, J., Tr. 154-55; HOJ, Feijo, P., Tr. 268-70). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

118. Respondent DCO paid for Respondent James Feijo to play golf at the Deer Creek Golf Course located behind his Deerfield Beach, Florida home. (CX 49; J. Feijo, HOJ Tr. 155).

Response to Finding No. 118

See Response to Finding No. 117.

119. Respondent DCO has an American Express Business Gold Card, which is also in Patricia Feijo's name, and to which Respondent James Feijo is a signatory. (CX 48).

Response to Finding No. 119

Respondents have no specific response other than to note that credit cards are a common and legal way to pay for personal and business expenses, and are used by all types of individuals and organizations, including religious non-profits and other charities. Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

120. Respondent James Feijo has frequently used the American Express Business Gold Card to eat at restaurants, play golf, buy cigars, and other retail items. (CX 48; J. Feijo, HOJ Tr. 151-60).

Response to Finding No. 120

Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive.

Trinidad v. Sagrada Orden de Predicadores, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956). The Feijos live modestly (R 15 (Feijo, J., Dep. at 79, 95-97, 217-20, 227); HOJ, Feijo, J., Tr. 183-84); HOJ, Mink, Tr. 299-300; HOJ, Harrison, Tr. 247). The uses identified above amount to approximately 3 percent of the total charges on this credit card (CX 48).

121. According to American Express statements for DCO's American Express Business Gold Card, approximately \$11,358 was charged for golf expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2985, 2995, 3003, 3004, 3011, 3039, 3049, 3081, 3082, 3091, 3092, 3103, 3104, 3111, 3113, 3119, 3129, 3171, 3174, 3181, 3182, 3189, 3208B, 3208C, 3208M, 3210, 3237, 3264, 3297).

Response to Finding No. 121

CX 48 does not support this proposed finding. Respondents' Counsel's calculation yields a total for golf expenses about \$1,282 lower than Complaint Counsel's calculation of \$11,358. This amount is approximately 1 percent of the total charges to the subject cards during the specified time period (CX 48). In addition, there are no charges for golf on page FTC-DCO 3297, as cited by Complaint Counsel. James Feijo uses golfing as an opportunity to spread his faith and minister to interested persons (HOJ, Feijo, J., Tr. 154-55; HOJ, Feijo, P., Tr. 268-70). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

122. According to American Express statements for DCO's American Express Business Gold Card, approximately \$14,024 was charged for restaurant expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2966, 2975, 2985, 2995, 2996, 3003, 3011, 3012, 3019, 3027, 3028, 3039, 3040, 3049, 3057, 3058, 3059, 3067, 3068, 3081, 3091, 3103, 3113, 3129, 3137, 3181, 3182, 3197, 3208A, 3208B, 3208K, 3208M, 3209, 3210, 3217, 3218, 3225, 3235, 3238, 3245, 3251, 3255, 3264, 3265, 3274, 3275, 3284).

Response to Finding No. 122

The amount alleged is about \$350 per month spent on eating at restaurants, which included payment not only for the Feijos' meals, but also for the meals of DCO's other members and associates at those restaurants (HOJ, Harrison, Tr. 257; HOJ, Bertrand, Tr. 300). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments

are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956). The Feijos often eat at restaurants because the Feijos work long hours and are often traveling for their ministry (HOJ, Feijo, J., Tr. 159; HOJ, Feijo, P., Tr. 261).

123. According to American Express statements for DCO's American Express Business Gold Card, approximately \$28,582 was charged for automobile expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2966, 2975, 3003, 3011, 3019, 3027, 3039, 3049, 3050, 3057, 3065, 3068, 3082, 3103, 3105, 3113, 3127, 3129, 3165, 3173, 3181, 3189, 3208B, 3231, 3238, 3245, 3264, 3265, 3271, 3273, 3284).

Response to Finding No. 123

Respondent DCO owns two cars to support its ministry. DCO also purchased a van, which bears DCO's name on its side window, for use by Jay Harrison for DCO's activities (HOJ, Tr. 280). Vehicle expenses incurred during business use of the vehicles are expenses in support of its charitable and religious purposes. 26 U.S.C. § 501(c)(3). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

124. According to American Express statements for DCO's American Express Business Gold Card, approximately \$1,077 was charged for cigar expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 3113, 3121, 3181, 3197, 3208M, 3245, 3264, 3273).

Response to Finding No. 124

The \$25 per month spent for cigars was to give the cigars as gifts for other

members and associates of DCO (HOJ, Feijo, J., Tr. 153). Under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

125. Respondent DCO also has credit cards with Bank of America and Chase Bank. (J. Feijo, HOJ Tr. 161).

Response to Finding No. 125

See Response to Findings No. 109 to 124. Respondents have no other specific response.

126. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$51,087 was electronically transferred from these checking accounts to Bank of America during the period February 2007 - March 2009. (CX 49 at FTC-DCO 3352, 3359, 3363, 3367, 3674, 3680, 3685, 3701, 3706, 3726, 3733, 3741, 3750).

Response to Finding No. 126

Respondents note that this is a transfer from one ministry account to another and therefore is not considered an expense under general accounting rules (HOJ, Feijo, J., Tr. 214-216).

127. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$30,277 was paid by check from DCO's Creation Science Funding account to Bank of America during the period January 2007 - April 2007. (CX 49 at FTC-DCO 3448, 3456, 3470, 3472, 3498).

Response to Finding No. 127

Respondents note that this is a transfer from one ministry account to another and therefore is not considered an expense under general accounting rules (J. Feijo, HOJ Tr. 214-216).

128. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$25,837 was paid by check from DCO's Creation Science Funding account to Chase Card Services during the period January 2007 - April 2007. (CX 49 at FTC-DCO 3441, 3464, 3470, 3493, 3497).

Response to Finding No. 128

Respondents note that this is a transfer from one ministry account to another and therefore is not considered an expense under general accounting rules (J. Feijo, HOJ Tr. 214-216).

129. Respondent James Feijo does not retain any receipts for his credit card purchases and credit card payments are automatically debited. (J. Feijo, HOJ Tr. 163-64).

Response to Finding No. 129

James Feijo follows his religious principles, which do not support maintaining records (R 15 (Feijo, J., Dep. at 22-25); HOJ, Feijo, J., Tr. 74, 76, 78, 198).

130. Respondent James Feijo does not have his own individual bank account. (J. Feijo, HOJ Tr. 208).

Response to Finding No. 130

James Feijo acts consistently with his religious principles in having no material possessions (R 15 (Feijo, J., Dep. at 70, 224); R 16 (Feijo, J., Dep. at 56)).

131. Respondent James Feijo pays his daughter Jill \$700 per week for her work at Daniel

Chapter One. (J. Feijo, HOJ Tr. 204-05).

Response to Finding No. 131

Jill Feijo works full-time for DCO, receives no other compensation from DCO, and lives in a mobile home (HOJ, Feijo, J., Tr. 205).

132. Although he personally paid income taxes prior to DCO's incorporation as a corporation sole, Respondent James Feijo has since stopped personally paying income taxes. (J. Feijo, HOJ Tr. 86).

Response to Finding No. 132

Respondent James Feijo has no personal income from Respondent DCO (R 15 (Feijo, J., Dep. at 192; R 16 (Feijo, P., Dep. at 54) and therefore has no taxable income. Furthermore, under federal law, payment of normal living expenses of a minister and his family is not considered a private benefit so long as the payments are not excessive. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

133. Respondents do not pay any state sales tax based on the sale of DCO products through the DCO Web site. (J. Feijo, HOJ Tr. 210).

Response to Finding No. 133

Respondent DCO does not sell its dietary supplements (R 15 (Feijo, J., Dep. at 146-47, 210-12) and therefore does not pay any state's sales tax.

C. Respondents Claim That Their Products Cure, Mitigate, Treat, Or Prevent Cancer Or Tumors

Respondents' Response:

Respondents Do Not Claim That Their Products Cure, Mitigate, or Prevent (the Complaint, at Paragraph 5, Does Not Even Allege That the Products Claim To Mitigate, Treat, Or Prevent) Cancer or Tumors (Nor Are Tumors a Disease or Even Necessarily Cancerous).

134. Respondents advertise their products on the Internet. (J. Feijo, Tr. 459, 464).

Response to Finding No. 134

Respondents have no advertising budget and do not advertise their dietary supplements or the existence of their websites (R 15 (Feijo, J., Dep. at 151-52); R 16 (Feijo, P., Dep. at 60-61); Feijo, J., Tr. 459, 464).

135. Respondents admit that they make the following representations:

Bio*Shark inhibits tumor growth;
Bio*Shark is effective in the treatment of cancer;
7 Herb Formula is effective in the treatment or cure of cancer;
7 Herb Formula inhibits tumor formation;
GDU eliminates tumors;
GDU is effective in the treatment of cancer;
BioMixx is effective in the treatment of cancer; and
Bio Mixx heals the destructive effects of radiation and chemotherapy.

(Answer ¶ 14.)

Response to Finding No. 135

Respondents deny, and have repeatedly denied, ever making the following representations:

Bio*Shark inhibits tumor growth (Feijo, P., Tr. 340);
Bio*Shark is effective in the treatment of cancer (Feijo, P., Tr. 341);
7 Herb Formula is effective in the treatment or cure of cancer (Feijo, P.,

Tr. 345);
7 Herb Formula inhibits tumor formation (Feijo, P., Tr. 345);
GDU eliminates tumors (Feijo, P., Tr. 351);
GDU is effective in the treatment of cancer (Feijo, P., Tr. 351-52); and
BioMixx is effective in the treatment of cancer (Feijo, P., Tr. 354)

With regard to "BioMixx heals the destructive effects of radiation and chemotherapy," Respondents submit that this, like all claims that Respondents actually make, is a structure or function claim permitted in support of dietary supplements. Respondents did make the following permissible structure/function claims:

"Bioshark is 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 . . ."

7 Herb Formula "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"

GDU "contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."

BioMixx "boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

136. DCO's Web site depicts pictures of the DCO Products next to the statement "Daniel Chapter One's Cancer Solutions." (R16 (P. Feijo, Dep. at 176-77); CX 12-15, CX 12A, CX 13A, CX 14A, CX 43).

Response to Finding No. 136

CX 12, CX 12A, CX 14, CX 14A, CX 15, and CX 43 do not support this

proposed finding. The quote, “Daniel Chapter One’s Cancer Solutions,” as cited by Complaint Counsel, does not appear next to the product pictures on CX 12, CX 12A, CX 14, CX 14A, or CX 15.

137. On their Web site dc1pages.com, Respondents publish information about the DCO Products, including, but not limited to, the following:

Supporting Products

To enhance 7 Herb Formula’s healing quantities Daniel Chapter One advises [sic] to get familiar with the supporting products below:

**CANCER
TREATMENT:**

**7Herb Formula
Bio*Shark
BioMixx
GDU Caps**

also

**Ezekiel Oil
topically**

(CX 18).

Response to Finding No. 137

Respondents concur. The statements from DCO’s website, as cited, indicate that these products are “supporting products” that can be used in conjunction with cancer treatments, whatever those may be. The cited statements clearly do not claim that the DCO products can cure, treat, or prevent cancer. The intended and most frequent audience of the DCO web pages are followers of the DCO ministry (R 15 (Feijo, J., Dep. at 151-52)), which advocates, based on biblical text and

teachings, that only God can cure disease (R 15 (Feijo, J., Dep. 90-95, 113-115); Feijo, J. Tr. 417, 424-428, 433-35, 442-444, 446-447, 449, 457; Feijo, P., 337-340, 342, 349, 356-357, 404, 412-413). DCO's website states: "The information on this website is intended to provide record and testimony about God and His creation. It is not intended to diagnose a disease." (R 16 (Feijo, P., Dep. at 183). It should therefore be inferred that followers of the DCO ministry would understand the wording on this page in light of the basic tenet of the religion, namely that DCO products help God treat imbalance within the body, and that these products can support whichever type of cancer treatment one decides to pursue.

138. In DCO's The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide, DCO recommends the following products for cancer:

CANCER

All types of Cancer

7*Herb FormulaTM

2 ounces in juice or water
(minimum intake)
2 times daily

Bio*Shark^{TM**}(for tumors only)**

2 - 4 capsules
3 times daily with meals

BioMixxTM (Boosts immune system)

4 - 5 scoops in soy milk
2 times daily

GDU CapsTM

3 - 6 capsules
3 times daily; ½ hr.
BEFORE meals

(CX 20).

Response to Finding No. 138

See Response to Finding No. 137. Respondents note that there is no claim that the products cure, treat, or prevent cancer or tumors in the statements cited above by Complaint Counsel. Respondents reiterate that they do not believe that its agents or any other agents can cure, treat, or prevent cancer, and therefore did not claim such. Respondents believe that the word “disease” in general, and words describing specific “diseases” in particular, are merely ways to linguistically refer to an imbalance in the body that only God, working through the body’s own innate healing capacity, can re-balance (R 15 (Feijo, J., Dep. at 90-95, 113-15); R 16 (Feijo, P., Dep. at 12, 30-32, 42-46, 115); Feijo, J., Tr. 417, 424-28, 433-35, 442-44, 446-47, 449, 457; Feijo, P. Tr. 337-40, 342, 349, 356-57, 404, 412-13).

139. Through the “Testimonies” tab on the danielchapterone.com Web site, Respondents provide the following titles for testimonials from their customers, who claim that DCO’s Products were effective in the cure, mitigation, treatment, or prevention of cancer or tumors:

Cancer, Bladder (Drew Dellinger)
Cancer, Breast Mass (Deloris Winter)
Cancer, Cancerous Lung Tumor (Douglas Meeks)
Cancer, Cancerous Tumor (Joe Rocha)
Cancer, Leukemia, Brain Tumor (Tracey Kulikowski)
Cancer, Prostate (Jim Givens)
Cancer, Prostate Cancer (Joe)
Special Forces Officer Overcomes Prostate Cancer
Cancer, Prostate (Sherman “Red” Smith)
Cancer, Renal Cell (Jim Hatfield)
Cancer, Skin (Pastor Wayne Harms)
Cancer, Stage 4 (Joseph Jungles)

(CX 17).

Response to Finding No. 139

See Respondents' Response to Finding No. 137 and No. 138. Here, Complaint Counsel does not allege that the testimonies section of DCO's website contains the words "cure," "treat," or "prevent" cancer, nor does the testimonies section of DCO's website contain those words. DCO's categorization of the statements, as cited by Complaint Council in its Proposed Finding No. 139, is wholly consistent with the suggested use of the products for supporting whichever approach the testimony-givers have chosen for their well-being. The above cited statements are third-party statements, in which people describe their condition after using DCO products, the truth of which has not been challenged, but the testimonies were not admitted as evidence of the truth of what they contained. The fact that these people saw their health improve after using the DCO products is wholly consistent with DCO's assertion that these products can support whichever approach one chooses in rebalancing one's physical condition, for which Respondents have offered expert support. In addition, Complaint Counsel's proposed finding once again includes the word "mitigate," which is not included in Complaint Counsel's charges (Complaint, Paragraph 5).

140. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Tracey Kulikowski that states: "I had contracted leukemia and had three inoperable tumors. 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%. . . . There are alternatives besides

chemo and radiation!” (CX 21 (emphasis in bold added)).

Response to Finding No. 140

See Responses 137-39. Respondents note that Complaint Counsel does not allege that the above quote contains the words “cure,” “treat,” or “prevent.”

Respondents also note that the author of the testimonial states, “When I decided not to do chemotherapy or radiation...”, thus indicating that the testifier chose the DCO products **after** deciding to forego chemotherapy. Respondents also note that the testifier did not discover the DCO products through the website or the radio program. The cited testimonial is consistent with DCO’s assertion that its products are a good support for whichever approach one chooses for one’s physical imbalances that lead to conditions, which are named “diseases” by conventional medicine. In the context of their religious philosophy, Respondents view such conditions as internal spiritual and bodily imbalances. (R 15 (Feijo, J., Dep. at 90-95, 113-15); R 16 (Feijo, P., Dep. at 12, 30-32, 42-46, 115); Feijo, J., Tr. 417, 424-28, 433-35, 442-44, 446-47, 449, 457; Feijo, P. Tr. 337-40, 342, 349, 356-57, 404, 412-13). Additionally, Tracey Kulikowski was offered as a witness and was present in the court room during the opening sessions of the hearing, and was denied the opportunity to testify. Ms. Kulikowski could have clarified the points cited by Complaint Counsel in this proposed finding of fact, but was denied the opportunity to do so. Finally, Ms. Kulikowski’s statement, like all other testimonials referenced by Complaint Counsel in this brief, is a third-party statement, the truth of which has not been challenged, but the testimonies were

not admitted as evidence of the truth of what they contained.

141. Respondent James Feijo was responsible for putting together BioGuide 3. (R15 (J. Feijo, Dep. at 243)).

Response to Finding No. 141

Respondents have no specific response.

142. Patricia Feijo was responsible for writing the BioGuide. (R16 (P. Feijo, Dep. at 20)).

Response to Finding No. 142

Respondents have no specific response.

143. Bio*Shark, 7 Herb Formula, GDU, and BioMixx all appear in Respondents' Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!. (CX 23; CX 24).

Response to Finding No. 143

The Cancer Newsletter is intended for sharing testimony from users of DCO's products (Feijo, J., Tr. 452) and does not use the words "cure," "treat," or "prevent".

144. The Cancer Newsletter is "strictly all about the products for cancer." (R15 (J. Feijo, Dep. at 143)).

Response to Finding No. 144

Once again, the seven words cited above by Complaint Counsel (taken from a 349-word exchange during cross-examination by Complaint Counsel) are wholly consistent with DCO's position that the Challenged Products can support

whatever choice an individual might make for fighting their cancer. This is the antithesis of a claim that the DCO products “cure,” “treat,” or “prevent” cancer. In addition, Complaint Counsel have quoted Respondent James Feijo out of context and in so doing have mischaracterized the content of what was said. As can be seen below, read within its context, Respondent James Feijo’s statement merely attempts to clarify the nature of the Cancer Newsletter, rather than the nature of the dietary supplements identified within it. The statements made do not claim that the products will treat, cure, or prevent cancer (R15 (J. Feijo, Dep. at 142-144)):

Q. Was there a time when Daniel Chapter One published a cancer newsletter?

A. No. We only did this one issue.

Q. Did you also do one two years later, or am I --

A. I think it was the same -- I think it was pretty much the same thing. I mean, you know, it may have been a reprint of this for -- maybe we changed the content somewhat, but I think it might have been almost identical as far as I remember. But it wasn't like we did a newsletter and a newsletter. It was just trying to get -- the purpose of it was -- I guess we called it a newsletter. I don't know why we called it a newsletter. It's more like just an information booklet, you know. It's really not a newsletter. It's more like a booklet, you know.

Q. Was it geared to people who didn't know anything about your products?

A. I don't -- it was geared to people who -- if I remember how this came about, was people calling in to the program would ask about the products, do we have information about it, do we do anything about it, so they heard the show and the program and they heard about these things and they wanted the information. I think that's -- I think that's pretty much why that -- this whole so-called newsletter came about.

Q. And even though --

A. I would have liked to have had a newsletter, but we didn't.

Q. And even though, recalling your testimony, Daniel Chapter One doesn't deal with diseases, you chose to highlight cancer quite prominently on this newsletter or this publication, didn't you?

A. Oh, it's strictly all about the products for cancer.

Q. Okay.

A. It wasn't a newsletter, a general newsletter. It was just -- it really wasn't a newsletter. It was an information booklet about products for cancer -- the people who had different cancers.

Q. Cancer?

A. Right.

Q. And who prepared the newsletter?

A. I think my wife and I did it together.

145. The Cancer Newsletter contains descriptions of various DCO products that "a person can choose to use to help them fight cancer." (P. Feijo, Tr. 399). These products include Bio*Shark, GDU, BioMixx, and 7 Herb Formula. (P. Feijo, Tr. 402-04).

Response to Finding No. 145

Once again, the words cited above by Complaint Counsel are wholly consistent with DCO's position that the Challenged Products can support whichever approach an individual might choose for fighting cancer and do not evidence an intention by Respondents to present their products to "cure," "treat" or "prevent" cancer. See Response to Finding No. 144 for the context in which the Cancer Newsletter was prepared.

146. Patricia Feijo was responsible for writing the Cancer Newsletter. (R16 (P. Feijo, Dep. at 26-28); P. Feijo, Tr. 395-96).

Response to Finding No. 146

See Response to Findings No. 144 to 146. Respondents have no further specific

response.

147. James and Patricia Feijo are not doctors. (R16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 404; J. Feijo, Tr. 416).

Response to Finding No. 147

Respondents have no specific response.

148. James Feijo never held a position where he had to use any skills involving medicine. (R15 (J. Feijo, Dep. at 47)).

Response to Finding No. 148

Respondents have no specific response.

149. James and Patricia Feijo are not research scientists. (R16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 405).

Response to Finding No. 149

Respondents have no specific response.

150. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated that “the FTC, the FDA, the Canadian Government don’t like the fact that we’ve told people about what to do about natural methods of health and healing, especially cancer.” (CX 5 at FTC-DCO 0506).

Response to Finding No. 150

Respondent James Feijo was expressing his opinion about how the FTC, FDA, and the Canadian government view his speech. James Feijo did not say that he made claims about healing cancer. The statement cited above by Complaint Counsel is consistent with DCO’s position that the Challenged Products can support whichever approach an individual might choose for fighting cancer.

151. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated the following: “And while 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.” (CX 8 at FTC-DCO 0612).

Response to Finding No. 151

Respondent James Feijo and Patricia Feijo do not believe in cancer as a disease (Feijo, P., Tr. 337-340, 342, 349, 356-357, 404, 412-413; R 16 (Feijo, P. Dep. 12, 30-32, 42-46, 115)). Patricia Feijo’s statement was not an advertisement or promotional statement, but rather was a protected expression of her religious belief that God ultimately controls the condition of the body. Dr. Miller has even implied that there is no such disease as “cancer” – there are only specific types of cancer (Miller, Tr. 177-79):

Q. That's -- let me ask you a question.

Do you understand the difference between the approval of a process -- a product or the allowing of a product to be sold and what the claims can be made for that product? Do you understand that distinction?

A. They go hand in hand. You develop a product to treat a specific disease, stage of disease, a specific subtype of disease, and that's what you get in your label, that's what you get approval for.

I don't know of any drug that's used to, quote, treat cancer.

Q. I'm sorry. Any drug that's --

A. I don't know of a single drug that's out there to treat cancer, whatever that means.

Every drug has a specific indication. A drug may be approved to treat nonsquamous, non-small cell lung cancer but not the other types. Another drug might be used to treat B-cell lymphomas but not T-cell lymphomas.

So each drug that's developed, each anticancer agent that's developed has a specific indication, first-line therapy, it might be second-line therapy, but it's not just broad. There's no single anticancer modality that could be used for all patients with cancer.

Q. You indicated that reduction of inflammation would be a useful occurrence in a cancer patient; is that correct?

A. Yes.

(Miller, Tr. 177-78).

BioShark

152. Respondents publish information about Bio*Shark, including, but not limited to, the following:

PRODUCTS

Bio*Shark: Tumors & Cysts

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 such as diabetic retinopathy and macular degeneration. . .

(Answer ¶ 7; CX 12; CX 12A; CX 43; R15 (J. Feijo, Dep. at 61, 100-101, 107); R16 (P. Feijo, Dep. at 156-57); P. Feijo, Tr. 341).

Response to Finding No. 152

R 15, at 61 and 100-101, does not support this finding. In fact, page 61 of R 15 consists of James Feijo's testimony that Respondents never made claims that BioShark and 7 Herb Formula treat, prevent, or cure cancer. Pages 100-101 of R 15 consist of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the alleged claims. Additionally, the statement cited above by Complaint Counsel does not mention cancer – tumors do not constitute cancer – and the statement made is a truthful report on the facts

about protein that inhibits the formation of new blood vessels and consists of a structure or function claim for a dietary supplement, as permitted by law (R 4 (LaMont, Expert Witness Report, at 40)).

153. Respondents publish information about Bio*Shark, including, but not limited to the following:

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™ . . . [emphasis added]
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]

(Answer ¶ 9; CX 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 61, 100-101, 110-111)).

Response to Finding No. 153

The statement cited above by Complaint Counsel specifically does not state that the products can cure, treat, or prevent cancer, and is consistent with Respondents' assertion that the Challenged Products can support whichever approach an individual might choose for fighting cancer. Further, R 15, at 61 and 100-101, does not support this finding. In fact, page 61 of R 15 consists of James Feijo's testimony that Respondents never made claims that BioShark and 7 Herb Formula treat, prevent, or cure cancer. Pages 100-101 of R 15 consist of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel.

154. In their BioMolecular Nutrition Product Catalog, next to the pictures of the BioShark bottles, Respondents state that “Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye disease.” (CX 17 at FTC-DCO 0061).

Response to Finding No. 154

See Response to Finding No. 152. Respondents further submit that this is a permissible structure or function claim. *See* 21 U.S.C. § 343(r)(6).

155. On a prior Daniel Chapter One Web site, Respondents stated “**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks.” (CX 18 at FTC-DCO 2032 (emphasis in original)).

Response to Finding No. 155

Respondents submit that this is a permissible structure or function claim. *See* 21 U.S.C. § 343(r)(6).

7 Herb Formula

156. 7 Herb Formula is a product that can be used by a person who is suffering from cancer. (R16 (P. Feijo, Dep. at 171)).

Response to Finding No. 156

Respondents note that this is a true statement that does not claim that 7 Herb Formula is intended to treat, cure or prevent cancer, and in text related to the citation in Complaint Counsel’s proposed finding of fact, Patricia Feijo makes a permissible structure or function claim that the product helps detoxify blood and promotes cell repair (R 16 (Feijo, P., Dep. at 170-71)).

157. Respondents publish information about 7 Herb Formula, including, but not limited to, the

following:

INFO CENTER

Cancer News.

7 Herb Formula

- purifies the blood
- promotes cell repair
- **fights tumor formation** [emphasis in original]
- fights pathogenic bacteria

...

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]

7*Herb Formula™... [emphasis added]

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]

(Answer ¶ 9; CX 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 60, 101, 110-11); P. Feijo, Tr. 345).

Response to Finding No. 157

R 15, at pages 60 and 101, does not support this proposed finding. Rather, page 60 of R 15 consists of James Feijo's testimony about the computer program that he wrote, and that 7 Herb Formula is a DCO product. Page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel. Respondents further submit that the statements cited above by Complaint Counsel do not claim that the Challenged Product is intended to treat, cure, or prevent any disease, and that the statements are consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting

cancer.

158. Respondents publish information about 7 Herb Formula, including, but not limited to, the following:

7 Herb Formula battles cancer.

Tracey was given no hope!

The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver. . .

This is Tracey's story in her own words as told in 1997: 'I had contracted leukemia and had three inoperable tumors. When I 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. . ."

(Answer ¶ 9; CX 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 60, 101, 110-11)).-

Response to Finding No. 158

See Response to Finding No. 140. Also, R 15, at pages 60 and 101, does not support this proposed finding. Rather, page 60 of R 15 consists of James Feijo's testimony about the computer program that he wrote, and that 7 Herb Formula is a DCO product. Page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel. Respondents further submit that the statements cited above by Complaint Counsel do not claim that the Challenged Product is intended to treat, cure, or prevent cancer or any disease, and that the statements are consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer.

159. In their BioMolecular Nutrition Product Catalog, next to the picture of the 7 Herb Formula bottle, Respondents state that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, fight pathogenic

bacteria and *tumor formation*.” (CX 17 at FTC-DCO 0061 (emphasis added)).

Response to Finding No. 159

Respondents submit that the statements do not claim that the Challenged Product is intended to treat, cure, or prevent any disease. Aside from the fact that “tumor” is not a synonym for “cancer,” Respondents further submit that a claim that a product “fights tumor formation” constitutes a structure or function claim, similar to the six other structure or function claims also listed above. The statement that the product fights tumor formation is not a claim to cure, treat, or prevent cancer, but rather a statement consistent with Respondents’ position that the Challenged Product can support whichever approach an individual might choose for fighting cancer.

160. In Respondents’ BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Buzz McKay: “I had beam radiation for *prostate cancer*. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later, it was down to 0.16! 7 Herb Formula is extremely well done - fantastic. I still take 2 ounces of *7 Herb Formula* every morning; I plan to stay on that forever! *I figure 6 ounces (2 morning, 2 afternoon, 2 evening) did such a good job fighting cancer*, 2 ounces is a good prophylaxis!” (CX 21 at FTC-DCO 0330 (emphasis added)).

Response to Finding No. 160

This is a third-party statement, the truth of which has not been challenged.

Respondents submit that the statements do not claim that the Challenged Product is intended to treat, cure, or prevent any disease, but rather a statement consistent with Respondents’ position that the Challenged Product can support whichever

approach an individual might choose for fighting cancer.

161. On their Web sites danielchapterone.com and dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: “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.” (CX 18 at FTC-DCO 0142; CX 30 at FTC-DCO 0493).

Response to Finding No. 161

The statement cited above by Complaint Counsel is a permissible structure or function claim that is consistent with Respondents’ position that the Challenged Product can support whichever approach an individual might choose for fighting cancer. Respondents further submit that the statement does not claim that the Challenged Product is intended to treat, cure, or prevent any disease. The statement specifically does not use the words “cure,” “treat,” or “prevent,” and indicates that the product can help in the battle against – not replace other choices for – tumors, which are not synonymous with cancer.

162. On their Web site dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: “The 7 Herb Formula has been used by patients involved in clinical studies in cancer clinics and sold in doctor’s offices around the country.” (CX 18 at FTC-DCO 0157).

Response to Finding No. 162

Respondents have no specific response.

163. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated the following: “Here’s a testimony from Pastor Wayne Hamm, Henderson, Nevada. He had the Gulf War illness. He was told that he needed surgery and radiation treatment for his cancer, that he developed skin cancer because of the Gulf War, he was exposed out there. He didn’t take it. He decided to use Daniel Chapter One 7 Herb Formula, internally and topically. He also used Ezekiel Oil topically, BioShark and GDU. My skin cleared up

after a few months in the late 1980s, early '99, I was told there was no trace of cancer. The FDA does not want us to let you know about this." (CX 5 at FTC-DCO 0603).

Response to Finding No. 163

Respondent James Feijo was sharing the testimony of a follower of his ministry.

Such testimony indicated that the testifier chose to use the DCO products and that his cancer subsequently disappeared. This statement was not contained in an advertisement or promotional material, but was contained in a testimonial consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer (CX 5 at FTC-DCO 0603).

164. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated that 7 Herb Formula is "great for cancer." (CX 8 at FTC-DCO 0691).

Response to Finding No. 164

Complaint Counsel has taken Patricia Feijo's statement out of context. Patricia Feijo never stated that 7 Herb Formula was great for treating cancer. Read within its context, Patricia Feijo's statement conveys that 7 Herb Formula neutralizes stomach acid, which helps cancer patients (CX 8 at FTC-DCO 0690-0691), and is consistent with Respondents' position that the Challenged Product can support whichever approach an individual might choose for fighting cancer:

TRISH FEIJO: Well, certainly, it's his prerogative. But I'll tell you what, the main thing, 7 Herb Formula, we use it to cure acid, it neutralizes acid, it can heal stomach problems.

JIM FEIJO: Aliments. Gut Aliments right away.

TRISH FEIJO: And it's the best thing for cancer. And he can do the Aliments if nothing else right now.

NANCY: Okay.

JIM FEIJO: Yeah.

NANCY: So, the 7 Herb Formula is -- you can drink it as a tea or as --

TRISH FEIJO: Right. You can drink it full strength, but most people put it in either hot water as a tea or even cold water and it doesn't taste bad. And, again, it's great for the acid, it's great for cancer. But, you know, again, that's up to him, his prerogative.

(CX 8 at FTC-DCO 0690-0691).

GDU

165. Respondents publish information about GDU, including, but not limited to, the following:

PRODUCTS

...

Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein - even that of unwanted **tumors** and cysts. This formula also helps to relieve pain and heal inflammation. . . .and as an adjunct to **cancer** therapy. [emphasis added]

(Answer ¶ 11; CX 14; CX 14A; CX 43; R15 (J. Feijo, Dep. at 101, 138-39); R16 (P. Feijo, Dep. at 185-86); P. Feijo, Tr. 351).

Response to Finding No. 165

The statements cited above clearly do not claim that GDU will treat, cure, or prevent cancer. They are statements that GDU can be an “adjunct” to cancer therapy, including digesting the protein of unwanted tumors, and as such, are consistent with Respondents’ position that the Challenged Product can support

whichever approach an individual might choose for fighting cancer. Further, R 15, at page 101, does not support this finding. Rather, page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel.

166. Respondents publish information about GDU, including, but not limited to, the following:

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™ . . . [emphasis added]
[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]

(Answer ¶ 9; CX 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 101, 110-11)).

Response to Finding No. 166

R 15, at page 101, does not support this proposed finding. Rather, Page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel. Additionally, Respondents' statements, as cited above by Complaint Counsel, do not claim that the Challenged Products are intended to treat, cure, or prevent any disease. Respondents' suggested use for the product is consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer.

167. In their BioMolecular Nutrition Product Catalog, next to the pictures of the GDU bottles,

Respondents state 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*.” (CX 17 at FTC-DCO 0062 (emphasis added)).

Response to Finding No. 167

See Response to Finding No. 165. As cited above by Complaint Counsel,

Respondents’ statement that the product can be used as an adjunct to cancer therapy is not a claim to treat, cure, or prevent cancer. The statement is consistent with Respondents’ position that the Challenged Product can support whichever approach an individual might choose for fighting cancer.

168. In Respondents’ BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Deloris Winter: “I went in for a breast examination by mammography. On 10/8/01 they said they found a mass that they believed was not cancerous, but benign. I began taking GDU six times a day: 2 before breakfast, 2 before lunch, and 2 before dinner, and in a month I went to my doctor for the breast examination, and he found nothing on either breast.” (CX 21 at FTC-DCO 0331; R16 (P. Feijo, Dep. at 190)).

Response to Finding No. 168

The statement cited above is clearly not a claim to cure, treat, or prevent cancer, since the testifier did not have cancer.

169. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo advised a consumer whose father was diagnosed with colon cancer that she should get her father “on . . . GDU, BioShark and 7 Herb Formula. And if you can get him to, you know, go right now to the website, How To Fight Cancer Is Your Choice, or you can get him a hard copy from our order center, while we have them. It’s what the FTC wants to shut us down over and they certainly want us to, you know, crash the website and they want to, you know, burn our material. They don’t want us circulating How To Fight Cancer Is Your Choice.” (CX 8 at FTC-DCO 0693 - 0694).

Response to Finding No. 169

There is no claim in the statements cited above that the Challenged Products are intended to treat, cure, or prevent cancer. The statements are consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer. In fact, Complaint Counsel has taken Patricia Feijo's statements out of context. Patricia Feijo actually said that "*whether or not he does surgery, it's the same products he should get on and that would be GDU, BioShark, and 7 Herb Formula*" [emphasis added] (CX 8 at FTC-DCO 0693 - 0694).

BioMixx

170. Respondents publish information about BioMixx, including, but not limited to, the following:

Bio*Mixx boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in **fighting cancer** and in healing the destructive effects of **radiation** and **chemotherapy** treatments. [emphasis added]

(Answer ¶ 13; CX 15; R15 (J. Feijo, Dep. at 101); P. Feijo, Tr. 354-55).

Response to Finding No. 170

On their face, the statements cited do not claim that BioMixx is intended to treat, cure, or prevent cancer. Rather, the statements indicate that BioMixx assists the body in fighting cancer and heals the effects of radiation and chemotherapy. These are clearly "adjunct-to-cancer-treatment" statements consistent with Respondents' position that the Challenged Product can support whichever approach an individual might choose for fighting cancer. Further, R 15, as cited by Complaint

Counsel, does not support this proposed finding. Rather, page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel. Respondents make only structure or function claims for which they have adequate substantiation. See Response to Findings No. 165 and 167.

171. Respondents publish information about BioMixx, including, but not limited to the following:

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™ . . . [emphasis added]
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]

(Answer ¶ 9; CX 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 101, 110-11)).

Response to Finding No. 171

See Response to Findings No. 165 to 170. Also, R 15, at page 101, does not support this proposed finding. Rather, page 101 of R 15 consists of James Feijo's testimony that DCO provides the Challenged Products, and makes no reference to the statements cited above by Complaint Counsel. Respondents have never made claims that the Challenged Products are drugs (R 15 (Feijo, J., Dep. at 89, 125, 130, 205); Feijo, J., Tr. 459; Feijo, P., Tr. 375, 379, 381, 393-94, 408). Respondents have never claimed that the Challenged Products cure, treat, or

prevent cancer (R 15 (Feijo, J., Dep. at 61, 87-88, 111-12, 132, 242); R 16 (Feijo, P., Dep. at 145, 168, 180, 183-84, 199, 221). The Challenged Products are a part of the DCO ministry, the overall thrust of which is that only God can heal us (R 15 (Feijo, J., Dep. at 90-95, 113-15); R 16 (Feijo, P., Dep. at 12, 30-32, 42-46, 115); Feijo, P., Tr. 337-40, 342, 349, 356-57, 404, 412-13; Feijo, J., Tr. 417, 424-28, 433-35, 442-44, 446-47, 449, 457).

172. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents state the following regarding BioMixx: "What separates BioMixx is that it was developed specifically to maximize the immune system, particularly for those individuals whose immune systems were compromised through chemotherapy and radiation." (CX 21 at FTC-DCO 0334).

Response to Finding No. 172

The statements do not claim that the Challenged Product is intended to treat, cure, or prevent cancer or any disease. Rather, the statements indicate that the products are to be used as an adjunct to chemotherapy and radiation, and are consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer.

173. In their Cancer Newsletter, entitled How To Fight Cancer is Your Choice!!!, Respondents state that BioMixx "is used to assist the body in **fighting cancer** and in healing the destructive effects of **radiation** and **chemotherapy** treatments." (CX 23 at FTC-DCO 0400 (emphasis added)).

Response to Finding No. 173

See Response to Findings No. 165 to 172. The statement does not claim that the Challenged Product is intended to treat, cure, or prevent cancer or any disease.

Rather, the statement indicates that the product is to be used to help the body fight cancer and to heal the effects of chemotherapy and radiation, which is clearly a claim that the product is an adjunct to cancer treatment. Such statement is consistent with Respondents' position that the Challenged Products can support whichever approach an individual might choose for fighting cancer.

D. Respondents Disseminate Claims About Their Products to Consumers

174. Respondents operate the Web sites www.danielchapterone.com, dclpages.com, and dclstore.com that provide information on the DCO Products. (Answer ¶ 5; R15 (J. Feijo, Dep. at 62, 232-33)).

Response to Finding No. 174

Respondents have no specific response.

175. DCO advertises its products on the DCO Web site. (J. Feijo, Tr. 459, 464).

Response to Finding No. 175

Respondent DCO does not advertise its products. Any assertion that DCO "advertises" its products through the DCO website would be a characterization given by Complaint Counsel. The evidence shows that most of the viewers and users of DCO's website are followers of DCO's ministry who visit DCO's website to obtain more information about DCO's products (R 15 (Feijo, J., Dep. 151-152)). Respondent DCO has no advertising budget (Feijo, J., Tr. 459, 464).

176. Respondents disseminate information about the DCO Products through written materials,

including, but not limited to, the BioGuide, the Cancer Newsletter, the Web sites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch." (CX 39; R15 (J. Feijo, Dep. at 103); Harrison, Tr. 303, 305, 309-10; P. Feijo, Tr. 325, 350, 380; J. Feijo, Tr. 452-54).

Response to Finding No. 176

Respondents have no specific response.

177. The radio program "Daniel Chapter One Health Watch" is carried by an eclectic group of AM radio stations. (Harrison, Tr. 309-10).

Response to Finding No. 177

Respondents have no specific response.

178. Respondents' publication, The Most Simple Guide to the Most Difficult Diseases, is available on the DCO Web site and anyone can still download it. (CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).

Response to Finding No. 178

There is no evidence that anyone has actually downloaded, or for that matter, obtained through a donation, the Most Simple Guide from DCO's website. The Most Simple Guide is difficult, if not impossible, to download (Feijo, J., Tr. 455).

179. The BioGuide and the Cancer Newsletter are also available on-line through DCO's Web site. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55; Tr. 264).

Response to Finding No. 179

Pages 453-55 of the Transcript, as cited by Complaint Counsel, do not support this proposed finding. Pages 453-55 refer only to the Most Simple Guide. There is no evidence that anyone has actually downloaded the BioGuide or Cancer

Newsletter.

180. Respondent James Feijo and his wife, Patricia Feijo, are responsible for the information contained in the written materials, including the BioGuide, the Cancer Newsletter, the Web sites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch," that describe the DCO Products. (CX 39; R15 (J. Feijo, Dep. at 62); P. Feijo, Tr. 350, 380, 395-96).

Response to Finding No. 180

Respondents have no specific response.

181. Consumers can locate Respondents' Web site by entering the term "cancer" in a Google search. (R15 (J. Feijo, Dep. at 136)).

Response to Finding No. 181

Respondent James Feijo did not state as a fact that a Google search for "cancer" would retrieve DCO's website, and was merely speculating that it may be possible to eventually come to the DCO website by doing a Google search for "cancer" (R 15 (Feijo, J., Dep. at 136)). Respondents also note that James Feijo did not use the word "consumer" in Complaint Counsel's above proposed finding (R 15 (Feijo, J., Dep. at 136)). Instead, James Feijo merely answered in the affirmative to Complaint Counsel's question, "*Somebody* could come to your website by Googling 'cancer'?" [emphasis added] (R 15 (Feijo, J., Dep. at 136)). Any assertion that "consumers" can locate DCO's website through a Google search for "cancer" is a characterization given by Complaint Counsel.

182. FTC Investigator Michael Marino found and accessed DCO's Web site www.danielchapterone.com through Microsoft Internet Explorer. (CX 1).

Response to Finding No. 182

Michael Marino was directed to DCO's website by Complaint Counsel (R 11 (Marino, Dep. at 16-18)).

183. Respondent James Feijo and his wife, Patricia Feijo, co-host the Daniel Chapter One radio program for two hours a day, Monday through Friday. (CX 39; R15 (J. Feijo, Dep. at 16-17); Harrison, Tr. 303; P. Feijo, Tr. 324; J. Feijo, Tr. 450-51).

Response to Finding No. 183

Respondents concur.

184. Respondents have counseled cancer patients who have called into the Daniel Chapter One radio program about taking the DCO Products. (R16 (P. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 221-22; P. Feijo, Tr. 360-64).

Response to Finding No. 184

Respondents concur.

185. The DCO radio program and the DCO Web site were the natural vehicle for Respondents to reach out to people in other states. (R16 (P. Feijo, Dep. at 62)).

Response to Finding No. 185

Complaint Counsel has misconstrued Patricia Feijo's statement. Patricia Feijo was merely speculating about the sequence of events – whether interested persons from out-of-state first heard about DCO's products through the radio show and website, or whether those interested persons had heard of DCO's products from other sources before DCO began its radio show and website (R16 (P. Feijo, Dep. at 96-97)). Patricia Feijo was not stating as a fact that DCO's radio show and website were the natural vehicle for Respondents to reach out to people in other

states.

E. Respondents Did Not Possess Substantiation For Such Claims At the Time They Were Made

186. Respondents represented to consumers that they possessed and relied upon a reasonable basis that substantiated the representations set forth in the FTC's Complaint. (Answer ¶ 15.)

Response to Finding No. 186

Respondent DCO provides dietary supplements as part of its ministry.

Respondent James Feijo and Patricia Feijo discuss the power of God with

Respondent DCO's followers. As discussed in more detail in the brief

accompanying this response, Respondents had adequate substantiation for their statements.

187. Respondents conducted no scientific testing on any of the DCO Products. (R16 (P. Feijo, Dep. at 161); R15 (J. Feijo, Dep. at 201-02); P. Feijo, Tr. 405).

Response to Finding No. 187

There has been a wide range of testing, including some double-blind studies, conducted on various chemical entity components of all the Challenged Products (Miller, Tr. 109; R 4 (LaMont, Expert Witness Report, at 8-39); R 18 (Duke, Dep. at 10-11, 20-21, 32-33 and 107); R 15 (Feijo, J., Dep. at 182-84, 186-89); R 16 (Feijo, P., Dep. at 58); Feijo, J., Tr. 458; Feijo, J., Tr. 458).

188. Respondents have not conducted any double-blind studies on the DCO Products. (R15 (J. Feijo, Dep. at 58, 205-06)).

Response to Finding No. 188

Double-blind studies are not required for substantiation of any FTC-regulated products, including dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

189. Respondents’ have not conducted any controlled studies on any of the DCO Products. (R15 (J. Feijo, Dep. at 54-55)).

Response to Finding No. 189

Controlled studies are not required for substantiation of any FTC-regulated products, including dietary supplements. *See FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

190. No person has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. (CX 39).

Response to Finding No. 190

There is no requirement that testing and research for dietary supplements be

conducted on persons. *See FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

191. Respondents have no documents relating to their policies, procedures, or requirements for evaluating or reviewing each safety, efficacy, or bioavailability representation made for the DCO Products. (CX 38).

Response to Finding No. 191

Respondents have no specific response.

192. It was not Respondents’ practice to obtain scientific studies about any of the components in their products. (R16 (P. Feijo, Dep. at 120)).

Response to Finding No. 192

Complaint Counsel has misconstrued Patricia Feijo’s statement. Respondents consulted numerous scientific studies and scientific sources for the components in their products (R 15 (Feijo, J., Dep. at 124-25, 182-84, 186-89); R16 (Feijo, P., Dep. at 58, 73-74, 99-103, 105-114, 118-27, 130-35, 137, 139-40, 147-51, 153, 162, 171-72, 186-88, 202); Feijo, J., Tr. 440-41, 458; Feijo, P., Tr. 350-52, 381, 401, 405, 408).

193. Respondents did not search for scientific studies regarding the components in their products because “[w]e’re working with people, and again, it’s experiential and it’s working with the whole person.” (R16 (P. Feijo, Dep. at 120)).

Response to Finding No. 193

See Response to Finding No. 192.

194. James Feijo agrees that individual results may vary and that what one person says in her testimonial may not apply to other people. (R15 (J. Feijo, Dep. at 141-42)).

Response to Finding No. 194

Respondents concur.

195. According to Patricia Feijo, “only God can cure cancer.” (R16 (P. Feijo, Dep. at 115)).

Response to Finding No. 195

Respondents concur.

196. According to Patricia Feijo, “We [James and Patricia Feijo] do have knowledge that is experiential. We have seen how these products work. God has shown us [James and Patricia Feijo] and given us a wealth of knowledge and information that - - and we felt it is very truthful and actually our duty to share with people.” (R16 (P. Feijo, Dep. at 116)).

Response to Finding No. 196

Respondents concur.

197. Patricia Feijo was unable to identify with specificity which articles she was relying upon specifically for the specific claims that brought about the charges in this case. (P. Feijo, Tr. 607-08).

Response to Finding No. 197

Patricia Feijo relied on all the articles which she supplied to the FTC to substantiate the claims for which the charges in this case are being brought (R16 (Feijo, P., Dep. at 99-103, 105-114, 118-27, 130-35, 137, 139-40, 147-51, 153, 202)).

BioShark

198. Respondents conducted no scientific testing on Bio*Shark. (R16 (P. Feijo, Dep. at 161)).

Response to Finding No. 198

There have been scientific studies on shark cartilage, which is the main component of BioShark (Miller, Tr. 88, 97; R 16 (Feijo, P., Dep. at 162); Feijo, P., Tr. 406, 408; Feijo, J., Tr. 449). Double-blind studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

199. Respondents’ substantiation for the statement that “[p]ure skeletal tissue of sharks . . . can stop tumor growth” is “from the material that [they] had read that shark cartilage provides a protein that inhibits angiogenesis and the information [they] have that [they] have . . . read and complied for many years now.” (R16 (P. Feijo, Dep. at 157)).

Response to Finding No. 199

After examining the scientific materials that Respondents used to substantiate their claims about BioShark, Dr. LaMont concluded that these scientific materials indeed show that shark cartilage inhibits angiogenesis (R 22 (LaMont, Dep. at 192)).

200. Patricia Feijo is not aware of any other studies that might have been done on Bio*Shark or shark cartilage other than Dr. Lane’s studies. (R16 (P. Feijo, Dep. at 162)).

Response to Finding No. 200

Respondents and/or Patricia Feijo have, and did provide, scientific materials regarding angiogenesis and its relation to shark cartilage on which they relied, including Lane, I. William; Comac, Linda; Sharks Don't Get Cancer: How Shark Cartilage Could Save Your Life 1992 (R9-a); Shark and Bovine Cartilage (R9-w); Lane, I.W., Contreras E.; Shark Cartilage Research: High Rate of Bioactivity (Reduction in Gross Tumor Size) Observed in Advanced Cancer Patients Treated With Shark Cartilage Material (R9-aa); Lee, Anne; Langer, Robert; Research Abstract: Shark Cartilage Contains Inhibitors of Tumor Angiogenesis September 1983 (R9-ab); Journal Articles; Shark Cartilage Contains Inhibitors of Tumor Angiogenesis (R9-ac); Lopez, Jose R. Menendez; Rodriguez, Jose E. Fernandez-Britto; Lane I.W. Journal Article: Shark Cartilage Administration in Human Advanced Cancer Diseases (R9-ae); Brem, Henry; Folkman, Judah; and Inhibition of Tumor Angiogenesis Mediated by Cartilage (R9-af)).

201. Although Respondents relied upon Dr. Lane's book, "Sharks Don't Get Cancer," for substantiation, Respondent James Feijo never read it. (J. Feijo, Tr. 449).

Response to Finding No. 201

Patricia Feijo read the book, Sharks Don't Get Cancer (R 16 (Feijo, P., Dep. at 162)).

202. Universal Nutrition did not conduct any testing, quality or otherwise, on Bio*Shark. (R17 (Bauhoffer-Kinney, Dep. at 45-46)).

Response to Finding No. 202

Respondents have no specific response.

7 Herb Formula

203. Respondents never had an outside lab study the components of 7 Herb Formula to see whether its components actually have the effect that Respondents believe it has. (R16 (P. Feijo, Dep. at 132)).

Response to Finding No. 203

Respondents did retain the services of an outside consultant who contracted with a well-known herbal formulation company to create 7 Herb Formula (R 19 (Dews, Dep. at 34-35, 56-57); Feijo, J., Tr. 441)). In addition, there is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

204. Rather than having an outside lab study the components of 7 Herb Formula to determine whether its components were actually having the effect Respondents believe, Respondents have “experiential information [and] many testimonies, many hundreds if not thousands of testimonies.” (R16 (P. Feijo, Dep. at 132)).

Response to Finding No. 204

Respondents relied on scientific evidence regarding the components of 7 Herb Formula (R 15 (Feijo, J., Dep. at 124-25); R 16 (Feijo, P., Dep. at 73-74, 171-72); (R 19 (Dews, Dep. at 34-35, 43-51); Feijo, P., Tr. 350, 381, 405; Feijo, J., Tr. 440-41). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

205. Respondents’ basis for asserting that using 7 Herb Formula will help someone with any

type of cancer is “their knowledge about the structure/function of the separate ingredients and the history of the herbal formally, so experientially . . . [they] can say generally that if you suffer from any type of cancer that [Respondents] suggest taking [7 Herb Formula].” (R16 (P. Feijo, Dep. at 175-76)).

Response to Finding No. 205

See Response to Finding No. 204.

GDU

206. GDU was never subjected to clinical trials. (R16 (P. Feijo, Dep. at 190)).

Response to Finding No. 206

Clinical trials are not required for dietary supplements. There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Double-blind studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”).

207. Respondents have not done any studies to know whether GDU would counteract with any conventional cancer medicine someone was taking. (R16 (P. Feijo, Dep. at 194)).

Response to Finding No. 207

See Response to Finding No. 206.

BioMixx

208. Respondents did not conduct any tests or clinical studies on BioMixx. (R16 (P. Feijo,

Dep. at 199)).

Response to Finding No. 208

Clinical trials are not required for dietary supplements. There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Double-blind studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”).

209. Respondents did not engage anybody else to do any kind of clinical tests on BioMixx. (R16 (P. Feijo, Dep. at 199)).

Response to Finding No. 209

See Response to Finding No. 208.

210. Respondents’ basis for asserting that BioMixx fights cancer is “[b]ased on the structure of the ingredients, what we know that to be, and based on the function of those ingredients, what we know that to be, and based on the experiential evidence, the witness of many.” (R16 (P. Feijo, Dep. at 199-200)).

Response to Finding No. 210

Respondents have adequate substantiation for their claims about BioMixx (R 22 (Lamont, Dep. at 121-123, 206-211); R 4 (LaMont, Expert Witness Report, at 40); R 3 (Duke, Expert Witness Report, at 13)).

211. Universal Nutrition has not conducted any testing on BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 50)).

Response to Finding No. 211

Respondents have no specific response.

F. Dr. Miller Confirms That There Is No Competent And Reliable Scientific Evidence To Substantiate The Claims That DCO'S Products Treat, Cure, Or Prevent Cancer

212. Denis R. Miller, M.D. is a board-certified pediatric hematologist/oncologist. Expert Report of Denis R. Miller, M.D., dated January 28, 2009, (hereinafter referred to as CX 52 at ___) at 1.

Response to Finding No. 212

Respondents have no specific response.

213. 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. (CX 52 at 1).

Response to Finding No. 213

Respondents have no specific response.

214. Dr. Miller also has served as Associate Medical Director of Cancer Treatment Centers of America ("CTCA") as well as Scientific Director of CTCA's Cancer Treatment Research Foundations. (CX 52 at 1).

Response to Finding No. 214

Respondents have no specific response.

215. As Scientific Director, Dr. Miller supervised the clinical research program and was principal investigator for a number of Phase I/II clinical studies involving treatments for hematological malignancies and cancers of the head and neck, lung, breast, pancreas, and colon. (CX 52 at 1-2).

Response to Finding No. 215

Respondents have no specific response.

216. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts, and has served on the editorial boards of the British Journal of Hematology and the American Journal of Clinical Oncology. (CX 52 at 3.)

Response to Finding No. 216

Respondents have no specific response.

217. Dr. Miller currently is the Oncology/Hematology Therapeutic Area Leader at PAREXEL International, a leading contract research organization, where he manages clinical trials for the pharmaceutical industry. (CX 52 at 2).

Response to Finding No. 217

Respondents have no specific response.

218. 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. (CX 52 at 7).

Response to Finding No. 218

Respondents' products are dietary supplements and do not purport to treat, cure, or prevent cancer. Furthermore, even products that do make health claims are not necessarily required to undergo controlled clinical studies for purposes of substantiation under the law governing the FTC. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), ("Placebo-controlled, double-blind testing is not a legal requirement for consumer products.") For health claims, the FDA Secretary has discretion in deciding whether the body of scientific evidence presented

constitutes sufficient substantiation. Structure/function claims for dietary supplements are permitted by law without government pre-approval. See 21 U.S.C. § 343 (r); FDA, *Claims that Can Be Made For Conventional Food and Dietary Supplements*, at 2-3 (2003); FDA, *Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers*, at 2 (2006). Also, the FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

219. 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. (CX 52 at 30).

Response to Finding No. 219

See Response to Finding No. 218.

220. Anecdotal reports of product efficacy are the weakest form of evidence supporting the anticancer activity of a new agent. (CX 52 at 12).

Response to Finding No. 220

Respondents do not assert that the testimonials from users of DCO's products constitute substantiation for their statements.

221. Testimonials do not substitute for a well-designed clinical trial in proving the efficacy of a supposed cancer fighting product. (CX 52 at 30).

Response to Finding No. 221

See Response to Finding No. 220.

222. Dr. Miller's 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. (CX 52 at 31).

Response to Finding No. 222

Respondents have made no claims that the Challenged Products treat or cure cancer, prevent the destructive effects of radiation or chemotherapy, or inhibit tumor formation. Respondents do say that the Challenged Products contain ingredients that assist the natural healing capacity of the body by strengthening the immune system, reducing inflammation, and assisting the body to cleanse or heal the by-products that come from tumors, radiation, and chemotherapy (Complaint, Exhibits A-D). Respondents have made only structure or function claims for the Challenged Products, which are dietary supplements. Dr. Miller is not an expert in dietary supplements and incorrectly asserts that only placebo-controlled, double-blind studies qualify as evidence of substantiation for claims for dietary supplements under the laws governing the FTC (Miller, Tr. 114, 150-52, 173-74, 204). In fact, double-blind studies are not required for substantiation of any FTC-regulated products, including dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

Bio*Shark

223. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates 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. (CX 52 at 13).

Response to Finding No. 223

Dr. Miller equates "competent and reliable scientific evidence" with placebo controlled, double-blind studies. The laws and regulations governing substantiation enforced by the FTC do not require double blind studies for consumer products including dietary supplements (see Complaint Counsel's Proposed Finding No. 222). Respondents do not claim that BioShark treats cancer (Complaint, Exh. 1; Feijo, P., Tr. 340-41). Instead, Respondents actually say, "*Bioshark is 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 . . .*" (Feijo, P., Tr. 341). Respondents have adequate substantiation for their claims regarding BioShark (see Response to Finding No. 200 and Dr. LaMont's testimony and expert witness report).

224. Dr. Miller found 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. (CX 52 at 17).

Response to Finding No. 224

Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204). Furthermore, the FTC has no fixed formula for the number or type of

studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

225. Dr. Miller observed 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. (CX 52 at 16).

Response to Finding No. 225

Respondents relied on numerous other studies and articles on shark cartilage (see Response to Finding No. 200 above) and read Dr. Lane's book which reports that sharks do not get cancer.

7 Herb Formula

226. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that 7 Herb Formula inhibits tumor formation and is effective in the treatment or cure of cancer in humans. (CX 52 at 18).

Response to Finding No. 226

Respondents do not claim that 7 Herb Formula treats, cures, prevents cancer, or that it inhibits tumor growth (Feijo, P., Tr. 345). Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204). See Response to Finding No. 223 and 224.

227. Dr. Miller 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. (CX 52 at 19).

Response to Finding No. 227

Respondents do not claim that 7 Herb Formula or its ingredients are effective

anticancer agents or that they inhibit tumor formation (Complaint, Exhibits A-D). Dr. Miller is not an expert on dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204). Also, the FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). There has been a wide range of testing, including some double-blind studies, conducted on various chemical entity components of all the Challenged Products (Miller, Tr. 109; R 4 (LaMont, Expert Witness Report, at 8-39); R 18 (Duke, Dep. at 10-11, 20-21, 32-33 and 107)).

228. 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. (CX 52 at 19-22).

Response to Finding No. 228

Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204). The FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). There has been a wide range of testing, including some double-blind studies, conducted on various chemical entity components of all the Challenged Products (Miller, Tr. 109; R 4 (LaMont, Expert Witness Report, at 8-39); R 18 (Duke, Dep. at 10-11, 20-21, 32-33 and 107)).

GDU

229. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that GDU eliminates tumors and is effective in the treatment of cancer in

humans. (CX 52 at 22).

Response to Finding No. 229

Respondents do not claim that GDU treats cancer or eliminates tumors (Feijo, P., Tr. 351-52). Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204). See Response to Finding No. 227.

230. Dr. Miller found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. (CX 52 at 27).

Response to Finding No. 230

The FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Furthermore, “[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also* 21 U.S.C. § 343 (r)(6).

231. Dr. Miller, however, 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. (CX 52 at 22).

Response to Finding No. 231

Respondents concur and reiterate that they did not claim that GDU or any of its ingredients is a chemo-protective or cancer-preventive agent

232. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. (CX 52 at 23).

Response to Finding No. 232

Respondents concur.

233. Nevertheless, Dr. Miller 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. (CX 52 at 27).

Response to Finding No. 233

Respondents have no specific response.

234. Thus, Dr. Miller advised that further research on curcumin was necessary. (CX 52 at 27).

Response to Finding No. 234

Respondents note that Dr. Miller was using the standard for substantiation for drugs and not for dietary supplements.

BioMixx

235. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates 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. (CX 52 at 27).

Response to Finding No. 235

Respondents do not claim that BioMixx is effective in the treatment of cancer. Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204) and was using the standard for substantiation for drugs and not for dietary supplements. The FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Furthermore, "[p]lacebo-controlled, double-blind

testing is not a legal requirement for consumer products.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also* 21 U.S.C. § 343 (r)(6). Respondents’ experts, Dr. Duke and Dr. LaMont, each testified that the information supplied by Respondents constituted adequate substantiation (R 4 (LaMont, Expert Witness Report, at 40); R 3 (Duke, Expert Witness Report, at 13)).

236. Dr. Miller found that there are no reported studies of either BioMixx or its constituent ingredients being effective in the treatment of cancer. (CX 52 at 27-28).

Response to Finding No. 236

Respondents do not claim that BioMixx is effective in the treatment of cancer. Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204) and was using the standard for substantiation for drugs and not for dietary supplements. The FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Furthermore, “[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also* 21 U.S.C. § 343 (r)(6).

237. Dr. Miller also found “absolutely no data” to support the claim that BioMixx is used to heal the destructive effects of radiation and chemotherapy treatments. (CX 52 at 29).

Response to Finding No. 237

Dr. Miller is not an expert in dietary supplements (Miller, Tr. 114, 150-52, 173-74, 204) and was using the standard for substantiation for drugs and not for dietary supplements. The FTC has no fixed formula for the number or type of

studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Furthermore, “[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also* 21 U.S.C. § 343 (r)(6). Respondents’ experts, Dr. Duke and Dr. LaMont, each testified that the information supplied by Respondents constituted adequate substantiation (R 4 (LaMont, Expert Witness Report, at 40); R 3 (Duke, Expert Witness Report, at 13)).

G. Respondents’ Purported Experts Do Not Possess Any Information Substantiating Respondents’ Claims and Reinforce Dr. Miller’s Conclusion that No Competent and Reliable Scientific Evidence Exists to Support Respondents’ Claims

Introduction

James Duke, Ph.D.

238. James Duke, Ph.D. (“Duke”) has never met Jim and Patricia Feijo. (Deposition of James Duke, Ph.D. (hereinafter referred to as R18 (Duke, Dep. at __)) at 8).

Response to Finding No. 238

Respondents have no specific response.

239. Duke is not a medical doctor. (R18 (Duke, Dep. at 56); Duke, Tr. 521).

Response to Finding No. 239

Respondents have no specific response.

240. Duke is not licensed to practice medicine in any state. (R18 (Duke, Dep. at 56); Duke, Tr. 521).

Response to Finding No. 240

Respondents have no specific response.

241. Duke is not a board-certified oncologist. (R18 (Duke, Dep. at 56); Duke, Tr. 521).

Response to Finding No. 241

Respondents have no specific response.

242. Duke does not recall ever publishing any articles in any peer-reviewed medical journals. (R18 (Duke, Dep. at 56); Duke, Tr. 521).

Response to Finding No. 242

Dr. Duke's MAMs have been cited in the Blue and Green books and in other standard herbal science materials (R 18 (Duke, Dep. at 113)).

243. Duke has never practiced medicine. (R18 (Duke, Dep. at 18)).

Response to Finding No. 243

Dr. Duke consults with people on what herbs to take for specific conditions (R18 (Duke, Dep. at 18)).

244. Duke would not recommend that people self-medicate with herbal remedies in treating cancer. (R18 (Duke, Dep. at 135)).

Response to Finding No. 244

Respondents have never recommended that people self-medicate or use DCO products to treat cancer. Patricia Feijo has always recommended to callers and other interested persons to seek the advice of a medical doctor (Feijo, P., Tr. 364,

382, 393).

245. Duke is sure that there is a risk that some people will pursue herbal medications instead of effective pharmaceutical medications and thereby die. (R18 (Duke, Dep. at 136)).

Response to Finding No. 245

Complaint Counsel has taken Dr. Duke's statement out of context. Cancer patients have a high risk of death, regardless of what kind of therapy they pursue. "[A] day didn't go by when one of my [cancer] patients died [sic]. And there was very little in the way of therapy for those patients." (Miller, Tr. 41).

246. Duke does not recall any holistic physicians who have consulted with him on the treatment of cancer. (R18 (Duke, Dep. at 19)).

Response to Finding No. 246

Complaint Counsel has taken Dr. Duke's statement out of context. Although Dr. Duke has not consulted with holistic physicians regarding cancer, he consults with them generally (R 18 (Duke, Dep. at 19); Duke, Tr. 522).

247. Duke does not recall any homeopaths who have consulted with him on the treatment of cancer. (R18 (Duke, Dep. at 19)).

Response to Finding No. 247

Complaint Counsel has taken Dr. Duke's statement out of context. Although Dr. Duke has not consulted with homeopaths regarding cancer, he consults with them generally (R 18 (Duke, Dep. at 29); Duke, Tr. 522).

248. Duke has never managed or participated in any studies to measure the efficacy of an herb in treating cancer. (R18 (Duke, Dep. at 19); Duke, Tr. 522).

Response to Finding No. 248

Dr. Duke has participated in studies of substances that may have a bearing on cancer and is an expert in herbs (R 3 at CV of James Duke appended to end of Expert Witness Report; R 18 (Duke, Dep. at 29)).

249. Duke does not remember ever being a consultant on a study where the anticancer effects of an herb were being measured on a group of patients. (R18 (Duke, Dep. at 29-30); Duke, Tr. 523).

Response to Finding No. 249

Respondents have no specific response.

250. Duke does not remember seeing the FTC's Complaint against Respondents. (R18 (Duke, Dep. at 36)).

Response to Finding No. 250

Respondents have no specific response.

251. Duke has no knowledge of any of the advertisements that the FTC has challenged as the predicate for the Complaint. (R18 (Duke, Dep. at 36-37); Duke, Tr. 534).

Response to Finding No. 251

With regard to Complaint Counsel's Proposed Findings No. 238 to 251, Respondents do not claim that the Challenged Products treat, cure, or prevent cancer (Complaint, Exhibits A-D). Respondents do not advertise and have no advertising budget (Harrison, Tr. 287; Feijo, J., Tr. 459-460).

252. Duke was not sent any of Respondents' products and has never seen them. (R18 (Duke, Dep. at 37); Duke, Tr. 524).

Response to Finding No. 252

Respondents have no specific response.

253. Duke has not spoken to any persons who have taken DCO products for the treatment of cancer. (R18 (Duke, Dep. at 38)).

Response to Finding No. 253

Respondents have no specific response.

254. Duke has not reviewed the medical records of anyone who claims to have taken DCO products for the treatment of cancer. (R18 (Duke, Dep. at 39)).

Response to Finding No. 254

Respondents have no specific response.

255. Duke had never heard of DCO until this case. (R18 (Duke, Dep. at 39)).

Response to Finding No. 255

Respondents have no specific response.

256. Duke remembers being quite surprised when he learned that most of the list of chemicals that Respondents were studying were not biblical. (Duke, Tr. 536.)

Response to Finding No. 256

Respondents have no specific response.

257. Duke has never listened to the DCO Radio program. (R18 (Duke, Dep. at 39)).

Response to Finding No. 257

Respondents have no specific response.

258. Duke knows of no tests where the patient prays and one group of patients gets a Biblically

referenced herb and the other group of patient prays and gets an allopathic treatment. (R18 (Duke, Dep. at 41-42)).

Response to Finding No. 258

Respondents have no specific response.

259. Duke does not think that “the FDA permits advertising for cancer unless clinically proven.” (R18 (Duke, Dep. at 46)).

Response to Finding No. 259

Respondents have no specific response.

260. Duke’s “Multiple Activity Menus” (“MAMs”) are an attempt to identify herbs that show promise in fighting disease. (R18 (Duke, Dep. at 91)).

Response to Finding No. 260

Respondents concur.

261. The MAM and the ratio that it yields does not prove that any one of these herbs is effective in fighting or treating cancer. Rather, “[i]t adds a listing of the chemicals in that herb that have been shown or assumed to help with cancer.” (R18 (Duke, Dep. at 92)).

Response to Finding No. 261

Respondents have no specific response except that the proposed fact conflates the concept of herbs with the ingredients in the herbs.

262. When entering in the MAM an activity for an herb, Duke only enters references to that source “as it may be a good source [or] it may be a bad source.” (R18 (Duke, Dep. at 93)).

Response to Finding No. 262

Respondents have no specific response.

263. Duke acknowledged that it is a “gut feeling” on how he makes sure that the studies he references in the MAMs are reliable. (R18 (Duke, Dep. at 108)).

Response to Finding No. 263

Dr. Duke is an expert on research regarding herbs and uses his expertise in evaluating the trustworthiness of a reference ((R 3 (Duke Expert Witness Report, 1-2 and attached CV)).

264. Duke acknowledged that his MAMs have not been cited in any peer-reviewed journal. (R18 (Duke, Dep. at 113)).

Response to Finding No. 264

Dr. Duke’s MAMs have been cited in the Blue and Green books and in other herbal scientific materials (R 18 (Duke, Dep. at 113)).

265. Duke explained that his Indication Evaluations (“IE”) is where he has “gone through all these abstracts over the years [and] I’ve scored for a given indication. If it’s folklore and that’s all I have, it would receive an ‘f’; if it has a chemical or an epidemiological or an animal or an in vitro evidence, I’ve given it a 1; and then the 2, as we mentioned earlier, that means it’s either been clinically approved - - an extract of the plant has been clinically approved or it’s been approved by the Commission E or the Tramil Commission for that indication. These are lines of evidence that point to me which ones are most important and should be studied for cancer.” (R18 (Duke, Dep. at 59, 118-19)).

Response to Finding No. 265

Respondents have no specific response.

266. The IE is a “compendium of information.” (R18 (Duke, Dep. at 109); Duke, Tr. 526).

Response to Finding No. 266

Dr. Duke analyzes and organizes the “compendium of information” in his writings (R 18 (Duke, Dep. at 109)).

267. There is no relationship between the MAMs and the IE. (R18 (Duke, Dep. at 92)).

Response to Finding No. 267

Respondents have no specific response.

268. Neither the MAMs nor the IE reflect information that indicates that turmeric, for example, is effective in the treatment of cancer. (R18 (Duke, Dep. at 109-10)).

Response to Finding No. 268

Turmeric's effectiveness in treating cancer is reflected in Dr. Duke's writings, which are based on the MAMs and the IE (R 18 (Duke, Dep. at 109-110)).

269. Duke has never measured the efficacy of herbs as a treatment for cancer in a controlled patient population. (R18 (Duke, Dep. at 55)).

Response to Finding No. 269

Dr. Duke has conducted a "fractionated MAM" (R 18 (Duke, Dep. at 55)). Also, controlled studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), ("Placebo-controlled, double-blind testing is not a legal requirement for consumer products."). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Respondents do not claim their products treat cancer.

270. Duke is not able to express opinions on what the minimum dosage would be necessary to achieve cancer-fighting. (R18 (Duke, Dep. at 67-68); Duke, Tr. 522-23).

Response to Finding No. 270

Complaint Counsel has misconstrued Dr. Duke's statement. Dr. Duke *is* able to express an opinion on the minimum dosage amount (R18 (Duke, Dep. at 67-68, 71), and his database contains some dosage suggestions derived from scientific research (Duke, Tr. 522-23).

271. Duke recognizes the difference between something being efficacious in an in vitro study and something being efficacious in human beings. (R18 (Duke, Dep. at 71); Duke, Tr. 523).

Response to Finding No. 271

Respondents have no specific response.

272. As a matter of science, Duke does not believe that the herbal extract working in vitro proves that it would work in a human. (R18 (Duke, Dep. at 77); Duke, Tr. 523).

Response to Finding No. 272

Respondents have no specific response.

273. Rather than relying solely on in vitro studies, Duke recommends "the third arm-trial where the whole plant or an extract thereof is compared with a competing pharmaceutical." (R18 (Duke, Dep. at 77)).

Response to Finding No. 273

Respondents concur.

274. According to Duke, "[t]he third arm would compare a given herb with a given pharmaceutical and placebo." (R18 (Duke, Dep. at 81)).

Response to Finding No. 274

Respondents concur.

275. Other than the St. John's Wort trial that used a placebo and Zoloft, Duke is not aware of

any other studies where an herb, a pharmaceutical, and a placebo were studied in a side-by-side manner. (R18 (Duke, Dep. at 82)).

Response to Finding No. 275

Respondents have no specific response.

276. Duke does not think of black cohosh as a major anticancer herb. (R18 (Duke, Dep. at 123)).

Response to Finding No. 276

Respondents have no specific response.

277. Duke stated that there is no reference to cancer in eleuthero because “that’s not one of the major things that are said about it.” (R18 (Duke, Dep. at 125-26)).

Response to Finding No. 277

Respondents have no specific response.

278. Most of the studies Duke has seen have been for preventing cancer. (R18 (Duke, Dep. at 128)).

Response to Finding No. 278

Respondents have no specific response.

279. Duke does not remember any studies specifically about treating cancer. (R18 (Duke, Dep. at 128-29)).

Response to Finding No. 279

Complaint Counsel has misconstrued Dr. Duke’s statement. Dr. Duke stated that he most likely has seen studies relating to treating cancer, but does not remember them specifically (R18 (Duke, Dep. at 128-29)).

280. Duke testified that anecdotal reports are “even below . . . my lines of evidence.” (R18 (Duke, Dep. at 131)).

Response to Finding No. 280

Respondents have no specific response. Respondents do not assert that the testimonials by users of DCO’s products constitute substantiation, nor do Respondents claim that DCO’s products cure, treat, or prevent cancer.

281. Duke attributes the increase in life expectancy in the 150 years that pharmaceuticals have been around to pharmaceuticals themselves. (R18 (Duke, Dep. at 133)).

Response to Finding No. 281

Complaint Counsel has misconstrued Dr. Duke’s statement. Dr. Duke answered in the affirmative to Complaint Counsel’s question, “Do you attribute *any* of [the increase in life expectancy] to pharmaceuticals?” [emphasis added] (R18 (Duke, Dep. at 128-29)). Dr. Duke never stated that he attributes the said increase in life expectancy completely to pharmaceuticals.

282. Duke does not believe that homeostatic balancing has been the subject of any peer-reviewed articles in connection with the treatment or cure of cancer. (R18 (Duke, Dep. at 133-34)).

Response to Finding No. 282

Respondents have no specific response.

283. In Duke’s IE, there have been no clinical trials as to the efficacy of black cohosh for cancer. (R18 (Duke, Dep. at 147)).

Response to Finding No. 283

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d

858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Respondents do not claim that their products cure, treat or prevent cancer.

284. There are no clinical trials regarding garlic’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 148)).

Response to Finding No. 284

See Response to Finding No. 283.

285. There are no clinical trials regarding Yellow Root’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 149)).

Response to Finding No. 285

See Response to Finding No. 283.

286. There are no clinical trials regarding eleuthero’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 153)).

Response to Finding No. 286

See Response to Finding No. 283.

287. There are no clinical trials regarding soybean’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 153-54)).

Response to Finding No. 287

See Response to Finding No. 283.

288. There are no entries for sarsaparilla in Duke’s IE indicating that it has been evaluated for

its efficacy in treating cancer in clinical trials. (R18 (Duke, Dep. at 156)).

Response to Finding No. 288

See Response to Finding No. 283.

289. The editors of Duke's book, The Green Pharmacy Guide to Healing Foods, advised Duke to "shy away from" a section on cancer treatment. (R18 (Duke, Dep. at 178)).

Response to Finding No. 289

Respondents have no specific response.

290. Duke does not recall seeing any articles that Mr. and Mrs. Feijo believe substantiated the claims that they made regarding the particular DCO Products. (R18 (Duke, Dep. at 185)).

Response to Finding No. 290

Respondents have no specific response.

291. Duke has made no effort to evaluate whether the combination of the ingredients in each of the products that DCO sells - GDU, 7 Herb Formula, and BioMixx – has any synergistic effects. (R18 (Duke, Dep. at 190); Duke, Tr. 525-26).

Response to Finding No. 291

Respondents have no specific response.

292. Duke made no effort to see whether there were any studies of any sort regarding the particular products that DCO sells - GDU, 7 Herb Formula, and BioMixx. (R18 (Duke, Dep. at 190-91)).

Response to Finding No. 292

Respondents have no specific response.

293. Duke is not familiar with any studies of GDU, 7 Herb Formula, or BioMixx. (Duke, Tr. 526).

Response to Finding No. 293

Respondents have no specific response.

294. Duke has not performed any tests or analyses on the DCO products himself. (Duke, Tr. 524).

Response to Finding No. 294

Respondents have no specific response.

James K. Dews

295. Respondents offer James K. Dews (“Dews”) as an expert in “[h]erbal formulations, specifically 7 Herb Formula.” (Deposition of James K. Dews (hereinafter referred to as R19 (Dews, Dep. at __)) at 4-5).

Response to Finding No. 295

Respondents have no specific response.

296. Dews attended the University of Texas at Arlington and Texas Wesleyan, but he did not finish college degrees at either institution. (R19 (Dews, Dep. at 11)).

Response to Finding No. 296

Respondents have no specific response.

297. According to Dews, nutraceuticals involves the merging of food supplements and pharmaceuticals. (R19 (Dews, Dep. at 17)).

Response to Finding No. 297

Respondents have no specific response.

298. Nutraceuticals involves the extraction of certain chemical compounds that are in many foods or herbs. (R19 (Dews, Dep. at 18)).

Response to Finding No. 298

Respondents have no specific response.

299. Consumers ingest nutraceuticals. (R19 (Dews, Dep. at 18)).

Response to Finding No. 299

Respondents have no specific response.

300. The difference between a pharmaceutical and a nutraceutical is that one can make a disease-curing claim with a pharmaceutical; one cannot make a disease-curing claim with a nutraceutical. (R19 (Dews, Dep. at 15, 62)).

Response to Finding No. 300

Respondents have no specific response.

301. According to Dews, animal studies cannot be extrapolated to humans. (R19 (Dews, Dep. at 63-64)).

Response to Finding No. 301

Complaint Counsel has misconstrued Mr. Dews's statements. Mr. Dews stated that animal studies can be an initial step in clinical studies to develop a drug. Mr. Dews emphasized that he was not making a judgment on whether animal studies could or could not be treated as conclusive of the drug's effect on humans. (R19 (Dews, Dep. at 63-65)).

Rustum Roy, Ph.D.

302. Respondents offer Rustum Roy, Ph.D. ("Roy") as "an expert in the conduct of scientific research and with the focus on health and materials." (Deposition of Rustum Roy, Ph.D. (hereinafter referred to as R20 (Roy, Dep. at __)) at 7).

Response to Finding No. 302

Respondents have no specific response.

303. Roy did not review the complaint that the FTC filed against Respondents. (R20 (Roy, Dep. at 7)).

Response to Finding No. 303

Respondents have no specific response.

304. Roy did not review any of the advertisements on which the FTC's complaint is predicated. (R20 (Roy, Dep. at 7)).

Response to Finding No. 304

Respondents have no specific response.

305. Roy did not review or obtain any of the product or product labels for the products at issue in the litigation. (R20 (Roy, Dep. at 7-8)).

Response to Finding No. 305

Respondents have no specific response.

306. Roy did not conduct any work or tests on any product made by Respondents. (R20 (Roy, Dep. at 8)).

Response to Finding No. 306

Respondents have no specific response.

307. Roy is not an expert in homeopathy. (R20 (Roy, Dep. at 12)).

Response to Finding No. 307

Respondents have no specific response.

308. Roy and his laboratory do “zero clinical trials.” (R20 (Roy, Dep. at 13)).

Response to Finding No. 308

Complaint Counsel has taken Dr. Roy’s statement out of context. Dr. Roy and his laboratory do not conduct clinical trials on the efficacy of products, but Dr. Roy and his laboratory do conduct studies on the structure of water and other substances (R 20 (Roy, Dep. at 13)).

309. Roy and his laboratory “have nothing to do with causing healing or not in a human being.” (R20 (Roy, Dep. at 13)).

Response to Finding No. 309

Respondents have no specific response.

310. Roy has not measured the efficacy of the DCO Products. (R20 (Roy, Dep. at 14)).

Response to Finding No. 310

Respondents have no specific response.

311. Roy has never done any experiments to measure the efficacy of any medical treatments “at the human level.” (R20 (Roy, Dep. at 14)).

Response to Finding No. 311

Respondents have no specific response.

312. Roy has no idea what the DCO Products contain. (R20 (Roy, Dep. at 24)).

Response to Finding No. 312

Respondents have no specific response.

313. Roy has not done any literature searches or any literature research concerning any of the

ingredients in DCO's products. (R20 (Roy, Dep. at 25)).

Response to Finding No. 313

Respondents have no specific response.

314. Roy does not have any formal training in medicine. (R20 (Roy, Dep. at 26)).

Response to Finding No. 314

Respondents have no specific response.

315. Roy has never treated or consulted with healers who were treating particular patients. (R20 (Roy, Dep. at 28)).

Response to Finding No. 315

Respondents have no specific response.

316. Roy does not know what Daniel Chapter One sells. (R20 (Roy, Dep. at 43)).

Response to Finding No. 316

Respondents have no specific response.

317. The practice of Daniel Chapter One selling products over the Internet to people that it had never seen, met, or examined the medical records for "obviously limits" homeopathy. (R20 (Roy, Dep. at 50)).

Response to Finding No. 317

Respondents have no specific response.

318. Roy's ideal description of homeopathy would not include selling products over the Internet to persons that the seller has not met. (R20 (Roy, Dep. at 51)).

Response to Finding No. 318

Respondents have no specific response.

319. It is not Roy's view that all herbal remedies are effective. (R20 (Roy, Dep. at 60-61)).

Response to Finding No. 319

Complaint Counsel has taken Dr. Roy's statement out of context. Dr. Roy has actually implied that not all pharmaceutical remedies can be effective for all persons because "The proposition that is used in RTCs [randomly controlled trials] is a statistical proposition, that I can get a certain distribution of effects if I have the same cause, and thereby I can say, well, it works." (R 20 (Roy, Dep. at 45). Because "[h]uman beings are not identical, ... typically randomly controlled trials do not apply to the process for many whole-person healing practices." (R 20 (Roy, Dep. at 46). In addition, Dr. Roy was offered as an expert to testify on the relationship between materials science and mental powers of healing, and not on whether herbal remedies are effective. As Complaint Counsel has acknowledged in its Proposed Finding No. 309, Dr. Roy and his laboratory "have nothing to do with causing healing or not in a human being."

320. Roy has never been involved in trying to secure FDA approval for some medication. (R20 (Roy, Dep. at 79)).

Response to Finding No. 320

Respondents have no specific response.

Sally B. LaMont, N.D.

321. Respondents offer Sally B. LaMont, N.D. ("LaMont") as "an expert in naturopathic

medical, herbal medicine, functional medicine . . . [and] as an expert on nutritional supplements and botanical medicines in the prevention and treatment of illness and as an expert in reviewing the evidence that supports the functional issues of the four products that are the challenged products.” (Deposition of Sally B. LaMont, N.D. (hereinafter referred to as R22 (LaMont, Dep. at __)) at 7-8).

Response to Finding No. 321

Respondents concur.

322. LaMont has never previously been asked to be an expert. (R22 (LaMont, Dep. at 54)).

Response to Finding No. 322

Respondents concur.

323. Lamont’s charge from Respondents is “to provide opinions on the use of nutritional supplements and botanical medicines in the prevention and treatment of illness, including but not limited to cancer, and to review the evidence that exists regarding the mechanisms of action of the major constituents of Daniel Chapter One’s products.” (R22 (LaMont, Dep. at 33)).

Response to Finding No. 323

Respondents concur.

324. LaMont is a naturopathic doctor. (R22 (LaMont, Dep. at 9, 15-16)).

Response to Finding No. 324

Respondents concur.

325. According to LaMont, naturopathic medicine “is a primary healthcare practice that focuses on health promotion and disease prevention and the treatment of disease with an array of natural therapies that strengthen the body’s innate healing capacities.” (R22 (LaMont, Dep. at 9)).

Response to Finding No. 325

Respondents concur.

326. Naturopathic doctors “provide patient-centered care and practice what would be termed functional medicine, which addresses the unique genetic, environmental and lifestyle factors that contribute to chronic disease and . . . influence our health.” (R22 (LaMont, Dep. at 9)).

Response to Finding No. 326

Respondents concur.

327. While engaged in naturopathic medicine, LaMont has worked in conjunction with traditional physicians. (R22 (LaMont, Dep. at 10)).

Response to Finding No. 327

Respondents concur.

328. In the course of doing a workup on a patient, if LaMont finds “a diagnosis that looks like it could be cancer,” she absolutely would refer the patient to a traditional physician and would comanage that patient’s care with the physician. (R22 (LaMont, Dep. at 10)).

Response to Finding No. 328

Respondents concur.

329. LaMont has not focused her naturopathic practice on naturopathic oncology; rather, she “ha[s] kept [her] practice very general.” (R22 (LaMont, Dep. at 11-12); LaMont, Tr. 576).

Response to Finding No. 329

Respondents have no specific response.

330. LaMont does not know what additional specialized training naturopathic oncologists take. (R22 (LaMont, Dep. at 12)).

Response to Finding No. 330

Respondents have no specific response.

331. LaMont has not done the specialized training for naturopathic oncology. (R22 (LaMont, Dep. at 12); LaMont, Tr. 576-77).

Response to Finding No. 331

Respondents have no specific response.

332. If LaMont ever found, for example, an abnormal pap smear with carcinoma inside, then she “would refer that patient to a gynecologist for a comprehensive workup and recommend that [her] patients follow the advice of their oncologist.” (R22 (LaMont, Dep. at 14)).

Response to Finding No. 332

Respondents concur.

333. LaMont’s understanding is that “cancer must be treated with conventional therapies.” (R22 (LaMont, Dep. at 15)).

Response to Finding No. 333

Respondents concur and note that Respondents do not purport to treat cancer through the use of the Challenged Products.

334. LaMont has seen conventional cancer therapies helpful in sometimes resolving the condition. (R22 (LaMont, Dep. at 15)).

Response to Finding No. 334

Respondents concur.

335. LaMont would always make a referral to a cancer specialist because “it’s an important part of the treatment of cancer at this point.” (R22 (LaMont, Dep. at 15)).

Response to Finding No. 335

Respondents have no specific response.

336. Fourteen states license N.D.s. (R22 (LaMont, Dep. at 17)).

Response to Finding No. 336

Respondents have no specific response.

337. A licensed naturopathic doctor's responsibilities are "to diagnose and to treat disease and to promote health, which is honestly the focus of our practice, to really strengthen our body's ability to heal itself." (R22 (LaMont, Dep. at 17)).

Response to Finding No. 337

Respondents concur.

338. The core of LaMont's practice is "[w]orking with diet and nutrition [and] nutritional supplements." (R22 (LaMont, Dep. at 20)).

Response to Finding No. 338

Respondents concur.

339. LaMont also uses botanical medicine. (R22 (LaMont, Dep. at 20)).

Response to Finding No. 339

Respondents concur.

340. LaMont works with mind-body therapies and regularly suggests meditation, qigong, yoga, and other biofeedback-type of therapies that would strengthen the person's connection between their mind and their immune system. (R22 (LaMont, Dep. at 20)).

Response to Finding No. 340

Respondents concur.

341. LaMont does acupuncture on most patients. (R22 (LaMont, Dep. at 20)).

Response to Finding No. 341

Respondents have no specific response.

342. Nutritional supplements come from food and are an extension of food. (R22 (LaMont, Dep. at 20)).

Response to Finding No. 342

Respondents concur.

343. Botanical medicine “comes from the plant world, and so there are phytochemicals in plants and then there’s the whole plant.” (R22 (LaMont, Dep. at 20-21)).

Response to Finding No. 343

Respondents concur.

344. Almost all the patients who come to LaMont who have been diagnosed with cancer come to her with that diagnosis and are looking for supportive care. (R22 (LaMont, Dep. at 23)).

Response to Finding No. 344

Respondents have no specific response.

345. LaMont thinks that the amount of dosage is important to the individual taking it and their health regimen. (R22 (LaMont, Dep. at 28)).

Response to Finding No. 345

Respondents have no specific response.

346. For someone who is in the “throes of chemotherapy,” LaMont would have them not to use many of their nutritional supplements the week that they are on chemotherapy. (R22 (LaMont, Dep. at 31)).

Response to Finding No. 346

Respondents have no specific response.

347. The reason why LaMont would advise someone not to use nutritional supplements during chemotherapy is because “we don’t fully understand yet all of the different ways in which this and other natural therapies may interact with chemotherapy.” (R22 (LaMont, Dep. at 31)).

Response to Finding No. 347

Respondents have no specific response.

348. LaMont only became familiar with DCO at the end of December 2008. (R22 (LaMont, Dep. at 22-23); LaMont, Tr. 577).

Response to Finding No. 348

Respondents have no specific response.

349. Prior to LaMont’s work on this case, she had never come across Bio*Shark, 7 Herb Formula, GDU, and BioMixx. (R22 (LaMont, Dep. at 34); LaMont, Tr. 578).

Response to Finding No. 349

Respondents have no specific response.

350. LaMont looked at the labels for the DCO Products and did a literature search on the main constituents of each of the products. (R22 (LaMont, Dep. at 34)).

Response to Finding No. 350

Respondents concur.

351. LaMont acknowledged that since they 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. (R22 (LaMont, Dep. at 47-48); LaMont, Tr. 579-82).

Response to Finding No. 351

Respondents concur and note that Respondents do not purport to cure, treat, or prevent cancer through the use of the Challenged Products. A basic tenet of the ministry is that God created humans with an innate healing capacity and that the way to approach health is to enhance that innate healing capacity. Followers of the DCO ministry understand this basic tenet of this religious belief (Feijo, J. Tr. 417, 424-428, 433-35, 442-444, 446-447, 449, 457; R 15 (Feijo, J., Dep. 90-95, 113-115); Feijo, P., 337-340, 342, 349, 356-357, 404, 412-413).

352. LaMont acknowledged that there have been no clinical studies performed on the DCO Products. (R22 (LaMont, Dep. at 48); LaMont, Tr. 579).

Response to Finding No. 352

Clinical studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

353. The DCO products “are not silver bullets.” (R22 (LaMont, Dep. at 127)).

Response to Finding No. 353

Respondents have no specific response.

354. LaMont does not know the Feijos. (R22 (LaMont, Dep. at 49)).

Response to Finding No. 354

Respondents concur.

355. LaMont 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.” (R22 (LaMont, Dep. at 49)).

Response to Finding No. 355

Respondents concur.

356. LaMont testified that “as a doctor, if I’m working with a patient, I’m going to insist that they work with their oncologist and follow their advice and I’m going to comanage their care.” (R22 (LaMont, Dep. at 51-52)).

Response to Finding No. 356

Respondents concur.

357. LaMont believes that “[t]he awareness of the powerful chemoprotective effects of plant foods and medicines should not influence patients with cancer and other serious diseases to abandon using the most effective methods that modern medicine has to offer.” (R22 (LaMont, Dep. at 52)).

Response to Finding No. 357

Respondents concur.

358. LaMont would not be comfortable with the Feijos saying that the DCO products are going to cure cancer. (R22 (LaMont, Dep. at 53)).

Response to Finding No. 358

Respondents concur and note that Respondents do not purport to cure, treat, or prevent cancer through the use of the Challenged Products. See Response to

Finding No. 351.

359. LaMont can see why the Federal Trade Commission would have concerns about the statement that DCO's products are cancer solutions. (R22 (LaMont, Dep. at 127)).

Response to Finding No. 359

See Response to Finding No. 351 above, and Respondents note that they claim that their products are intended to treat, cure, or prevent any disease.

360. LaMont would not have written the text that way to include "cancer solutions" next to the DCO products. (R22 (LaMont, Dep. at 128)).

Response to Finding No. 360

See Response to Finding No. 353 above for the full text and context of Dr.

LaMont's answer.

361. LaMont does not "believe that on their own across the board these [DCO] products are going to effectively treat cancer." (R22 (LaMont, Dep. at 53)).

Response to Finding No. 361

Dr. LaMont stated, "I think that [the DCO products] can be used to adjunctively treat ... cancer" (R 22 (LaMont, Dep. at 53)). Furthermore, Respondents' products do not purport to cure, treat, or prevent cancer (see Response to Finding No. 359 and Section C above).

362. LaMont did not listen to the Feijo's radio show nor did she have the interest in listening to their show. (R22 (LaMont, Dep. at 77)).

Response to Finding No. 362

Respondents have no specific response.

363. LaMont did not say that she would defend the DCO products because she has limited knowledge of their products. (R22 (LaMont, Dep. at 78)).

Response to Finding No. 363

Dr. LaMont's task in this proceeding was to "organize the body of evidence that related to the constituents of [the challenged DCO products]," which she was comfortable doing (R22 (LaMont, Dep. at 78)).

364. LaMont has never used the DCO products. (R22 (LaMont, Dep. at 78); LaMont, Tr. 578-79).

Response to Finding No. 364

Respondents concur but note that Dr. LaMont testified that after studying the products, she might use similar products (Mr. Zang is the questioner and Dr. LaMont is answering) (R 22 (Lamont Dep. at 149-151)):

Q. And can you just elaborate, please, on what you mean by "the potency necessary to achieve the desired therapeutic outcome." Why is potency important?

A. Well, I'm using these products in my practice often as pharmacological agents. There is that concept of nutritional pharmacology where nutrients, we know how they act to influence metabolism, and we're doing what's called precursor loading where we're putting in the nutrients that fuel a particular biochemical reaction and drive it to completion.

So the doctor's lines of products have been designed in a sense as medicine, whereas my perspective is these are meant to be used more as food and taken perhaps on a daily basis for longer periods of time. I may have a person on a supplement in my practice for several months and then have them off of that because we've achieved a therapeutic outcome.

Q. So in contradistinction to Daniel Chapter One's products, the ones you tend to use have higher potency?

A. They may. But not always. Not always. Some of these doses are more consistent with the ones that I have.

Q. Of the four products we've been discussing today -- we haven't fully discussed BioMixx, but including BioMixx and the three others we've discussed at length, which ones have the potency that you like to see, if any of them?

A. Well, the GDU is a product that looks to me like it has some good, strong therapeutic benefit, and that's -- you know, I happen to use other ones that are comparable, but that's within this line one that strikes me as potentially quite effective. And not that the others don't. I have personally in my practice never used any of the essiac tea formulas. I might think about it now after this and especially, you know, looking at the chemistry behind the constituents.

Q. Would you use --

A. I can see that it has some therapeutic value I may have underestimated before.

Q. And how about Bio*Shark or a product like it? Would you use that in your practice now?

A. I probably would not. I think that there's other ways to inhibit angiogenesis that are more certain, green tea, for example, and it's one that's present in the BioMixx coming up. I believe that's where it is. I get some of these products confused. Green tea is in one of these.

365. LaMont has not studied the DCO products specifically. (R22 (LaMont, Dep. at 87-88); LaMont, Tr. 579).

Response to Finding No. 365

Dr. LaMont did study the Challenged Products. Complaint counsel cite to a section of Dr. LaMont's deposition transcript in which she is describing a book (*Anticancer: A New Way of Life*) she recently read. The author of the book, an oncologist, developed a brain tumor, was treated with conventional chemotherapy and radiation, but on further study concluded that there are naturally-occurring compounds that can prevent and limit the growth of cancer, and that his

conclusions are related to the findings of the Feijos. It was that doctor (the author) who did not study the Challenged Products (R 22 (LaMont Dep. 83-88)).

366. LaMont acknowledges that traditional use evidence does not replace human clinical trials. (R22 (LaMont, Dep. at 89); LaMont, Tr. 584).

Response to Finding No. 366

Respondents concur and note again that federal law does not require human clinical trials for dietary supplements. The FTC has no fixed formula for the number or type of studies that constitute adequate substantiation. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Furthermore, “[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also* 21 U.S.C. § 343 (r)(6).

367. LaMont acknowledges that it is not a common occurrence in the industry to make cancer cure or cancer treatment claims. (R22 (LaMont, Dep. at 144-45)).

Response to Finding No. 367

Respondents concur and state again that they do not intend their products to treat, cure, or prevent any disease.

368. LaMont does not know of other companies that make claims that their products treat or cure cancer. (R22 (LaMont, Dep. at 145)).

Response to Finding No. 368

Respondents concur and state again that they do not intend their products to treat, cure, or prevent any disease.

369. Until there are clinical trials, LaMont agrees that “we don’t know” whether DCO’s products would effective in battling cancer. (R22 (LaMont, Dep. at 147); LaMont, Tr. 585).

Response to Finding No. 369

Respondents need only substantiate the claims they make, a topic which is discussed in more detail in the brief submitted with the response to this proposed finding of fact. The complete paragraph from which Complaint Counsel quote is:

“I feel confident that these – that the owners of this company were certainly doing the best they could and in their mind had created a suite of products that would be effective in battling cancer. Until we have clinical studies, we don’t know. We know that they attempted to formulate a group of products that would address the multiple challenges facing cancer patients, and that how I look at this.” (R 22 (LaMont, Dep. 147-148).

370. LaMont “wouldn’t want to have anybody say, [t]ake this, it’s going to cure your colon cancer.” (R22 (LaMont, Dep. at 161)).

Response to Finding No. 370

Respondents concur, as Respondents’ products do not purport to cure cancer. Dr. LaMont also stated that it would be accurate for Respondents to say, for example, that “turmeric and bromelain and parthenolides and chrysanthemum affect multiple aspects of carcinogenesis” (R22 (LaMont, Dep. at 160-61)).

371. LaMont thinks the approach of referring to some doctors as Dr. Dumb-Dumb, as James Feijo does on his radio show, is disrespectful. (R22 (LaMont, Dep. at 166)).

Response to Finding No. 371

Respondents have no specific response.

372. LaMont agrees that there is a danger if consumers do not continue with traditional cancer therapy. (R22 (LaMont, Dep. at 166)).

Response to Finding No. 372

Respondents do not encourage cancer patients to forego traditional cancer therapy (Feijo, P., Tr. 364, 393). Respondents' website directs readers to consult with medical professionals (CX 18 FTC-DCO 0133, 0135, 0138, 0143, 0147, 0150, 0153, 0156, 0158, 0161, 0163, 0165, 0168, 0171, 0174, 0177, 0180, 0184, 0189, and continuing at the bottom of each web page re-printed through page FRC-DCO 0288).

373. LaMont personally does not think that the Feijos should be suggesting that people should not get colonoscopies, as they suggest on their radio show. (R22 (LaMont, Dep. at 182)).

Response to Finding No. 373

As supported by Complaint Counsel's Proposed Finding No. 362, Dr. LaMont has never listened to the Feijos' radio show. Complaint Counsel even acknowledged that it had read the excerpt from the radio show to Dr. LaMont out of context (R22 (LaMont, Dep. at 180)). The Feijos do not suggest for people to forego colonoscopies (Feijo, P., Tr. 364).

374. LaMont recognizes that there is always that danger that people will take DCO products and not go and see their physicians. (R22 (LaMont, Dep. at 183)).

Response to Finding No. 374

Complaint Counsel has taken Dr. LaMont's statement out of context. Following the above statement, Dr. LaMont stated that there is always the general danger that people will "do whatever they want to do" (R22 (LaMont, Dep. at 183)).

375. LaMont has never conducted a scientific controlled study of any sort. (R22 (LaMont, Dep. at 184); LaMont, Tr. 577).

Response to Finding No. 375

Respondents have no specific response.

376. LaMont does not take any DCO products. (R22 (LaMont, Dep. at 184-85)).

Response to Finding No. 376

Respondents have no specific response.

377. LaMont has not reviewed the medical records of anyone who has taken DCO products. (R22 (LaMont, Dep. at 185); LaMont, Tr. 577-78).

Response to Finding No. 377

Respondents have no specific response.

378. LaMont has not spoken to any cancer patients who are or have been taking DCO products. (LaMont, Tr. 583).

Response to Finding No. 378

Respondents have no specific response.

BioShark

James Duke, Ph.D.

379. Duke is not offering opinions on BioShark “[b]ecause the major ingredient is an animal, and I don’t deal in animals.” (R18 (Duke, Dep. at 63)).

Response to Finding No. 379

Respondents have no specific response.

380. Duke was not asked to provide an opinion on BioShark. (R18 (Duke, Dep. at 64)).

Response to Finding No. 380

Respondents have no specific response.

381. Duke does not think highly of the studies that have been published on shark cartilage. (R18 (Duke, Dep. at 64); Duke, Tr. 527).

Response to Finding No. 381

As Complaint Counsel has acknowledged in its Proposed Finding No. 379 and No. 380, Dr. Duke was not asked to provide an opinion on BioShark or on shark cartilage. Dr. Duke stated that he was not an expert on animal ingredients (R 18 (Duke, Dep. at 63)).

382. Duke “was not convinced of the efficacy of shark cartilage in the studies that [he] read.” (R18 (Duke, Dep. at 64)).

Response to Finding No. 382

See Response to Finding No. 381.

James K. Dews

383. Dews never has heard of Bio*Shark. (R19 (Dews, Dep. at 53)).

Response to Finding No. 383

Respondents have no specific response.

384. Dews is not familiar with the use of shark cartilage in the treatment of cancer, and he has never seen any data relating to the use of shark cartilage in the treatment of cancer. He only has heard of this. (R19 (Dews, Dep. at 54)).

Response to Finding No. 384

Respondents have no specific response.

Sally B. LaMont, N.D.

385. LaMont does not know whether the product Bio*Shark inhibits tumor growth. (R22 (LaMont, Dep. at 91)).

Response to Finding No. 385

Respondents do not claim that BioShark cures, treats, or prevents cancer. Dr.

LaMont reviewed the published studies on shark cartilage and concluded, “There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.” (R 4, Expert Witness Report of Sally LaMont, N.D.

L.Ac. at 40).

386. LaMont does not know whether Bio*Shark is effective in the prevention, treatment, or cure of cancer. (R22 (LaMont, Dep. at 92); LaMont, Tr. 580).

Response to Finding No. 386

See Response to Finding No. 385.

387. LaMont acknowledged that there are no well-controlled studies demonstrating that the product Bio*Shark is antiangiogenic. (R22 (LaMont, Dep. at 101)).

Response to Finding No. 387

Controlled studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Dr. LaMont reviewed the published studies on shark cartilage and concluded, “There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.” (R 4, Expert Witness Report of Sally LaMont, N.D. L.Ac. at 40).

388. LaMont stated that there are no studies on Bio*Shark that are controlled clinical trials demonstrating its effectiveness. (R22 (LaMont, Dep. at 101)).

Response to Finding No. 388

Controlled studies are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a

legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Dr. LaMont reviewed the published studies on shark cartilage and concluded, “There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.” (R 4, Expert Witness Report of Sally LaMont, N.D. L.Ac. at 40).

389. LaMont does not know of any good or reliable data on the amount of antiangiogenic activity per gram of shark cartilage. (R22 (LaMont, Dep. at 112)).

Response to Finding No. 389

Based on the data available, Dr. LaMont was able to express the opinion that, “There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.” (R 4, Expert Witness Report of Sally LaMont, N.D. L.Ac. at 40)

390. LaMont agreed that it would be ideal to study variables such as the bioavailability, the absorption, and the distribution of Bio*Shark in order to assess its effectiveness with respect to cancer. (R22 (LaMont, Dep. at 101-102)).

Response to Finding No. 390

Respondents have no specific response.

391. LaMont probably would not use Bio*Shark or a product like it in her practice because she thinks that there are other ways to inhibit angiogenesis that are more certain. (R22 (LaMont, Dep. at 151)).

Response to Finding No. 391

Based on the data available, Dr. LaMont was able to express the opinion that, “There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.” (R 4, Expert Witness Report of Sally LaMont, N.D. L.Ac. at 40)

7 Herb Formula

James Duke, Ph.D.

392. Duke has no idea how much Burdock root in vitro would be necessary to eliminate cancer. (R18 (Duke, Dep. at 72); Duke, Tr. 528).

Response to Finding No. 392

Complaint Counsel has misconstrued Dr. Duke’s statement. Dr. Duke stated that he may be able to determine the amount of the anti-lymphomic substances that is necessary to arrest or prevent a lymphoma in vitro, after consulting his database and library (R18 (Duke, Dep. at 72); Duke, Tr. 528). Burdock root is not a Challenged Product (Complaint at 1-5).

393. Duke understands that four of the herbs in 7 Herb Formula are the “Essiac formula [that] have had both positive and negative trials published in PubMed.” (R18 (Duke, Dep. at 73)).

Response to Finding No. 393

Four of the seven herbs in 7 Herb Formula are not a Challenged Product (Complaint at 1-5). Dr. Duke believes that the elements in 7 Herb Formula would interact positively in terms of efficacy (R18 (Duke, Dep. at 73)). Based on available data, Dr. Duke expressed the opinion that “There is a reasonable basis for the claims that the ingredients of 7 Herb Formula ‘ ..., fights tumor formation, and fights pathogenic bacteria.’” (R18 (Duke, Dep. at 73)).

394. Duke does not know how much of the elements that are in 7 Herb Formula are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 528).

Response to Finding No. 394

Respondents have no specific response.

395. Duke acknowledged that although two of the lignans in Burdock have shown antilymphomic properties, they probably were in vitro. (R18 (Duke, Dep. at 125)).

Response to Finding No. 395

The lignans in Burdock root are not a Challenged Product (Complaint at 1-5).

396. There are no clinical trials regarding Burdock’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 148); Duke, Tr. 530).

Response to Finding No. 396

Dr. Duke was only examining Burdock in the context of lymphoma, which is one type of cancer (R18 (Duke, Dep. at 148)). Clinical trials are not required for

dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Also, Burdock root is not a Challenged Product (Complaint at 1-5).

397. There is no indication in Duke’s IE that watercress has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 154); Duke, Tr. 531).

Response to Finding No. 397

Respondents do not claim that this product will cure, treat, or prevent cancer (Complaint, Exhibits A-D). Respondents have repeatedly stated that clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

398. There is no indication in Duke’s IE that turkey rhubarb has been evaluated in clinical trials to treat cancer. (R18 (Duke, Dep. at 155); Duke, Tr. 531).

Response to Finding No. 398

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal

requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Also, rhubarb is not a Challenged Product (Complaint at 1-5).

399. There is no indication in Duke’s IE that sheep sorrell has been evaluated in clinical trials to measure its efficacy in treating cancer. (R18 (Duke, Dep. at 153); Duke, Tr. 532).

Response to Finding No. 399

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Also, sheep sorrel is not a Challenged Product (Complaint at 1-5).

400. There is no indication in Duke’s IE that slippery elm has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 532).

Response to Finding No. 400

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Also, slippery elm is not a Challenged Product (Complaint at 1-5).

401. There is no indication in Duke's IE that Cat's Claw has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 532).

Response to Finding No. 401

Clinical trials are not required for dietary supplements. *FTC v. QI, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), ("Placebo-controlled, double-blind testing is not a legal requirement for consumer products."). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Also, Cat's Claw is not a Challenged Product (Complaint at 1-5).

402. Duke "do[es]n't think much of the Essiac formula." (R18 (Duke, Dep. at 129); Duke, Tr. 528).

Response to Finding No. 402

Essiac formula is not one of the challenged products (Complaint at 1-5). 7 Herb Formula is composed of "the four original essiac substances" plus watercress, Cat's Claw, and Siberian Ginseng (Feijo, P., Tr. 439) and was designed by two herbalists contracted by Respondents. (R 15 (Feijo, J., Dep. at 124-25); R 16 (Feijo, P., Dep. at 74-75); Feijo, J., Tr. 441).

403. Duke acknowledged that sheep sorrel is "touted" for cancer in the Essiac formula. (R18 (Duke, Dep. at 129); Duke, Tr. 532).

Response to Finding No. 403

See Response to Finding No. 402.

404. Duke would recommend Slippery Elm "more for stomach problems, mucous problems.

It's famous for that." (R18 (Duke, Dep. at 130); Duke, Tr. 532).

Response to Finding No. 404

See Response to Finding No. 402. Also, slippery elm is not a Challenged Product (Complaint at 1-5).

405. Slippery Elm "is not one of the first things in [Duke's] cancer category." (R18 (Duke, Dep. at 130)).

Response to Finding No. 405

See Response to Finding No. 402. Also, slippery elm is not a Challenged Product (Complaint at 1-5).

James K. Dews

406. Dews "never heard of the 7 Herb Formula until this [lawsuit]." (R19 (Dews, Dep. at 59)).

Response to Finding No. 406

Respondents have no specific response.

407. According to Dews, 7 Herb Formula is a neutraceutical. (R19 (Dews, Dep. at 62)).

Response to Finding No. 407

Respondents have no specific response.

408. Dews is not prepared to talk about how the herbs in 7 Herb Formula may or may not benefit somebody with cancer. (R19 (Dews, Dep. at 39)).

Response to Finding No. 408

Respondents concur. Because Mr. Dews is the designer of the 7Herb Formula, he

is an expert on the purposes for which the constituent herbs in 7 Herb Formula have been used and what studies have been conducted on these herbs (R19 (Dews, Dep. at 39)).

409. Dews has never seen any controlled studies regarding 7 Herb Formula and its effectiveness in treating cancer. (R19 (Dews, Dep. at 58)).

Response to Finding No. 409

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Based on available data, Mr. Dews expressed the following opinion:

“I share the idea that the body has its own healing capacity. These seven herbs put together would assist the innate healing capacity of the body. Most of these things are an anti-inflammatory, and one of the definitions of a disease is inflammation of soft tissue. Like I keep saying, I don’t know that it rises to the level of claiming a cure of a disease state, but it certainly would very likely be of some benefit. If nothing else than making the person using them, more comfortable.” (R 6 (Expert Witness Report of James Dews at 14).

410. Dews has never seen any studies that would say that 7 Herb Formula is effective in curing cancer. (R19 (Dews, Dep. at 58-59)).

Response to Finding No. 410

Complaint Counsel’s proposed finding is irrelevant, as Mr. Dews is offered as an expert on the purposes for which the constituent herbs in 7 Herb Formula have been used and what studies have been conducted on these herbs (R19 (Dews, Dep.

at 39)). Respondents need only substantiate the claims they make, and they have not claimed that 7 Herb Formula cures cancer (Complaint, Exhibits A-D).

411. Dews does not know of any studies on whether 7 Herb Formula prevents cancer. (R19 (Dews, Dep. at 59)).

Response to Finding No. 411

Complaint Counsel's proposed finding is irrelevant, as Mr. Dews is offered as an expert on the purposes for which the constituent herbs in 7 Herb Formula have been used and what studies have been conducted on these herbs (R19 (Dews, Dep. at 39)). Respondents need only substantiate the claims they make, and they have not claimed that 7 Herb Formula prevents cancer (Complaint, Exhibits A-D).

412. Dews is not familiar with any studies that say there is anticancer activity in any of the components from the herbs contained in 7 Herb Formula. (R19 (Dews, Dep. at 16-24)).

Response to Finding No. 412

R 19, as cited by Complaint Counsel, does not support this proposed finding. Rather, pages 16-24 of R 19 consist only of Mr. Dews's testimony establishing the type of work that Mr. Dews is involved in. Further, Respondents only make claims regarding 7 Herb Formula's effects on the structure or function of the body (Complaint, Exhibits A-D).

413. Dews is not aware of any studies showing that 7 Herb Formula inhibits tumor formation. (R19 (Dews, Dep. at 59)).

Response to Finding No. 413

Respondents do not claim that 7 Herb Formula inhibits tumor formation
(Complaint, Exhibits A-D).

414. Other than “folk-wise” uses of the herbs contained in 7 Herb Formula as a folk remedy for cancer, there have not been any scientific studies done on the herbs found in 7 Herb Formula relating to their effectiveness as a remedy for cancer treatment. (R19 (Dews, Dep. at 45-46)).

Response to Finding No. 414

There have been studies on all the components of 7 Herb Formula pertaining to their overall effect on the body (R19 (Dews, Dep. at 50)). For example, there are many studies indicating that sheep sorrel, slippery elm, and watercress are effective in reducing inflammation (R19 (Dews, Dep. at 45-49)).

415. Dews does not recall seeing cancer mentioned specifically in any studies relating to burdock root. (R19 (Dews, Dep. at 44)).

Response to Finding No. 415

Studies have indicated that Burdock root reduces inflammation (R19 (Dews, Dep. at 43-44)). Respondents need only substantiate the claims they make, and they have not claimed that Burdock root cures, treats, or prevents cancer (Complaint, Exhibits A-D).

416. Dews has never “seen it stated that [Siberian ginseng] helps with cancer.” (R19 (Dews, Dep. at 46)).

Response to Finding No. 416

Siberian ginseng is used to give a person energy (R19 (Dews, Dep. at 46)).

Siberian ginseng is not a Challenged Product (Complaint at 1-5). Respondents

need only substantiate the claims they make, and they have not claimed that Siberian ginseng “helps with cancer” (Complaint, Exhibits A-D).

417. Dews has not ever seen any studies that have found that Siberian ginseng reduces tumors. (R19 (Dews, Dep. at 47)).

Response to Finding No. 417

See Response to Finding No. 416.

418. Dews has never seen any studies showing that slippery elm can help with, for example, stomach cancer. (R19 (Dews, Dep. at 49)).

Response to Finding No. 418

Studies have indicated that slippery elm reduces inflammation (R19 (Dews, Dep. at 49)). Respondents need only substantiate the claims they make, and they have not claimed that slippery elm helps with stomach cancer (Complaint, Exhibits A-D).

419. Dews has never seen any actual scientific studies done that would show that slippery elm can cure any disease. (R19 (Dews, Dep. at 50)).

Response to Finding No. 419

Studies have indicated that slippery elm reduces inflammation and that it may be helpful in a disease involving inflammation (R19 (Dews, Dep. at 49-50)).

Respondents need only substantiate the claims they make, and they have not claimed that slippery elm can cure any disease (Complaint, Exhibits A-D).

420. Dews has not seen any scientific studies on rhubarb root relating to treating cancer. (R19 (Dews, Dep. at 51-52)).

Response to Finding No. 420

Studies have indicated that turkey rhubarb root purifies the blood (R19 (Dews, Dep. at 51-52)). Regarding Complaint Counsel's Proposed Finding No. 404 to 418, Respondents reiterate that they do not intend for their products to be used to cure, treat or prevent cancer or tumors. Their products are intended to perform functions adjunctive to whatever approach an individual takes to dealing with cancer.

Sally B. LaMont, N.D.

421. LaMont does not know whether 7 Herb Formula is effective in the prevention, treatment, or cure of cancer. (R22 (LaMont, Dep. at 105); LaMont, Tr. 579-80).

Response to Finding No. 421

Respondents do not claim that 7 Herb Formula is effective in the prevention, treatment or cure of cancer (Complaint, Exhibits A-D). Dr. LaMont was not offered to express her expert opinion on 7 Herb Formula's effectiveness on preventing, treating, or curing cancer. Respondents need only substantiate the claims that they do make. Based on available data, Dr. LaMont expressed the following opinion: "There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria." (R 4 (LaMont Expert Witness Report at 40)).

422. LaMont "do[es]n't think that 7 Herb Formula is going to cure cancer." (R22 (LaMont, Dep. at 205)).

Response to Finding No. 422

See Response to Finding No. 421.

423. LaMont acknowledged that there are no clinical studies on this particular [7 Herb] formula. (R22 (LaMont, Dep. at 106)).

Response to Finding No. 423

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

424. LaMont does not know about the doses in 7 Herb Formula. (R22 (LaMont, Dep. at 104); LaMont, Tr. 582).

Response to Finding No. 424

Dr. LaMont was not offered to express her expert opinion on 7 Herb Formula’s formulation. Mr. Dews, the formulator of 7Herb Formula, testified regarding the formulation (R 19 (Dews, Dep. at 39)). Based on available data, Dr. LaMont expressed the following opinion: “There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.” (R 4 (LaMont Expert Witness Report at 40)).

425. LaMont does not know whether essiac has ever been evaluated in clinical trials to determine if it has any anticancer activity. (R22 (LaMont, Dep. at 106-07)).

Response to Finding No. 425

Siberian ginseng is not a Challenged Product (Complaint at 1-5). Also, clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

426. LaMont testified that “[i]t would be a stretch to suggest that this [7 Herb Formula] is on its own going to be effective in treating cancer.” (R22 (LaMont, Dep. at 117)).

Response to Finding No. 426

Respondents do not claim that 7 Herb Formula is effective in treating cancer (Complaint, Exhibits A-D). Dr. LaMont was not offered to express her expert opinion on 7 Herb Formula’s effectiveness on treating cancer. Respondents need only substantiate the claims that they do make. Based on available data, Dr. LaMont expressed the following opinion: “There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.” (R 4 (LaMont Expert Witness Report at 40)).

427. LaMont “would be concerned about patients taking [7 Herb Formula] on its own and expecting their cancer to go away.” (R22 (LaMont, Dep. at 118)).

Response to Finding No. 427

See Response to Finding No. 426.

428. LaMont stated that “[i]t would be a stretch for [her] that [7 Herb Formula] is a solution to cancer.” (R22 (LaMont, Dep. at 120)).

Response to Finding No. 428

Respondents do not claim that 7 Herb Formula is a solution to cancer (Complaint, Exhibits A-D). Respondents need only substantiate the claims that they do make. Based on available data, Dr. LaMont expressed the following opinion: “There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.” (R 4 (LaMont Expert Witness Report at 40)).

429. Lamont “would be surprised if [7 Herb Formula] itself is the solution to cancer.” (R22 (LaMont, Dep. at 120)).

Response to Finding No. 429

See Response to Finding No. 428.

430. LaMont would have a concern if 7 Herb Formula was advertised as a cancer solution. (R22 (LaMont, Dep. at 120-21, 123)).

Response to Finding No. 430

See Response to Finding No. 428.

431. LaMont does not know whether the amount of cat’s claw in 7 Herb Formula is going to be effective. (R22 (LaMont, Dep. at 129)).

Response to Finding No. 431

Cat’s claw is not a Challenged Product (Complaint at 1-5). Respondents need only substantiate the claims they make, and they have not claimed that cat’s claw,

independently of the remaining ingredients in 7 Herb Formula, will be effective
(Complaint, Exhibits A-D).

432. LaMont acknowledged that we do not know whether 7 Herb Formula as an independent agent would have any beneficial effects in respect to ovarian cancer.--(R22-(LaMont, Dep. at 137)).

Response to Finding No. 432

Respondents do not claim that 7 Herb Formula as an independent agent would have any beneficial effects in respect to ovarian cancer (Complaint, Exhibits A-D). Respondents need only substantiate the claims that they do make. Based on available data, Dr. LaMont expressed the following opinion: "There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria." (R 4 (LaMont Expert Witness Report at 40)).

433. LaMont personally has never used any of the essiac tea formulas in her practice. (R22 (LaMont, Dep. at 150)).

Response to Finding No. 433

Respondents concur. As Complaint Counsel has acknowledged in its Proposed Finding No. 349, prior to Dr. LaMont's work on this case, she had never come across Bio*Shark, 7 Herb Formula, GDU, and BioMixx.

434. LaMont does not think it is a good idea to take 7 Herb or GDU instead of having a polyp in the colon cut out. (R22 (LaMont, Dep. at 182-83)).

Response to Finding No. 434

Respondents concur; Respondents do not tell their followers to never have surgery (Feijo, P., Tr. 364).

GDU

James Duke, Ph.D.

435. Duke does not know how much of the elements that are in GDU are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 533).

Response to Finding No. 435

Dr. Duke was offered as an expert to testify regarding the components of the DCO products and their effects on the human body, and not to testify about the formulations of the products or the products themselves (R 3 (Duke, Expert Witness Report)). There has been no charge made or evidence offered that GDU or any of the other challenged products lack potency (Complaint at 1-5). Based on the available data, Dr. Duke expressed the following opinion: “There is a reasonable basis for the claims that the ingredients of GDU, ‘contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. GDU is also used for ... and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity ...’” (R 3 (Duke, Expert Witness Report, at 13)).

436. Duke testified that he saw two or three studies on turmeric, “but they were not conclusive.” (R18 (Duke, Dep. at 120); Duke, Tr. 533).

Response to Finding No. 436

Studies on curcumin, a primary ingredient in turmeric, are conclusive (Duke, Tr. 533).

437. Duke is not sure whether turmeric is more effective in fighting cancer than curcumin in an isolated form. (R18 (Duke, Dep. at 137)).

Response to Finding No. 437

Respondents have no specific response but note that, since turmeric contains curcumin, anyone consuming turmeric also consumes curcumin.

438. Duke does not remember any clinical studies on Bromelain. (R18 (Duke, Dep. at 124); Duke, Tr. 533).

Response to Finding No. 438

There are other types of studies on Bromelain (R18 (Duke, Dep. at 124)). Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Dr. Lamont testified as to the clinical studies on bromelain (R 22 (LaMont Dep. at 69-74)).

439. Duke testified that Feverfew is “not the first thing I think about when I’m thinking cancer.” (R18 (Duke, Dep. at 129-130)).

Response to Finding No. 439

Respondents do not claim that their supplements cure, treat, or prevent cancer. Rather, Respondents claim that GDU can be used as an adjunct to cancer and other therapy, and that GDU enhances the immune system, reduces inflammation, and creates other balances necessary for an individual's well-being. Also, feverfew is not a challenged product (Complaint, Exhibits A-D). Respondents need only substantiate the claims they make.

440. There are no clinical trials regarding pineapple Bromelain's efficacy as to cancer in Duke's IE. (R18 (Duke, Dep. at 148)).

Response to Finding No. 440

There are other types of studies on Bromelain (R18 (Duke, Dep. at 124)). Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), ("Placebo-controlled, double-blind testing is not a legal requirement for consumer products."). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001). Additionally, there are published clinical studies of bromelain (R 22 (LaMont Dep. at 72-33)).

441. Based on his review, there are no clinical trials regarding turmeric's efficacy as to cancer in Duke's IE. (R18 (Duke, Dep. at 153); Duke, Tr. 533).

Response to Finding No. 441

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), ("Placebo-controlled, double-blind testing is not a legal

requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

442. There are no indications in Duke’s IE that Feverfew has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 533-34).

Response to Finding No. 442

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

James K. Dews

443. Dews is not familiar with the product GDU. In fact, he does not have a clue what GDU is. (R19 (Dews, Dep. at 55)).

Response to Finding No. 443

Respondents have no specific response.

444. The active chemical in turmeric is curcumin, and curcumin is “very good at reducing inflammation.” (R19 (Dews, Dep. at 65)).

Response to Finding No. 444

Respondents have no specific response.

445. One cannot say that reducing inflammation is a cure for any particular disease. (R19 (Dews, Dep. at 66)).

Response to Finding No. 445

Respondents do not claim that the Challenged Products cure disease (Complaint, Exhibits A-D; R 16 (Feijo, P., Dep. at 145, 168, 180, 183, 184, 199 & 221); R 15 (Feijo, J., Dep. at 61, 87-88, 111-112, 132, 242)).

Sally B. LaMont, N.D.

446. LaMont does not know whether the product GDU eliminates tumors. (R22 (LaMont, Dep. at 92)).

Response to Finding No. 446

Respondents do not claim that GDU eliminates tumors (Complaint, Exhibits A-D). In addition, Dr. LaMont was not asked to express her expert opinion on whether GDU eliminates tumors. Based on the available data, Dr. LaMont expressed the following opinion: "There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains turmeric, feverfew and quercetin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents." R 4 (Expert Witness Report of Sally

LaMont, N.D. at 40).

447. LaMont does not know whether GDU is effective in curing cancer. (R22 (LaMont, Dep. at 43); LaMont, Tr. 581-82).

Response to Finding No. 447

Respondents do not claim that GDU cures cancer (Complaint, Exhibits A-D), or any other disease R 16 (Feijo, P., Dep. at 145, 168, 180, 183, 184, 199 & 221); R 15 (Feijo, J., Dep. at 61, 87-88, 111-112, 132, 242)).

448. LaMont does not know whether GDU is effective in the treatment of cancer. (R22 (LaMont, Dep. at 92); LaMont, Tr. 581).

Response to Finding No. 448

Respondents do not claim that GDU is effective in the treatment of cancer (Complaint, Exhibits A-D). Respondents are only required to substantiate the claims they do make.

449. LaMont is not aware of any clinical studies of GDU. (R22 (LaMont, Dep. at 42-43)).

Response to Finding No. 449

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

450. LaMont agrees that it would be fair to stay that it's impossible today to state the degree to which GDU is effective in the treatment or cure of cancer. (R22 (LaMont, Dep. at 45-46)).

Response to Finding No. 450

Respondents do not claim that GDU treats or cures cancer (Complaint, Exhibits A-D), or any other disease R 16 (Feijo, P., Dep. at 145, 168, 180, 183, 184, 199 & 221); R 15 (Feijo, J., Dep. at 61, 87-88, 111-112, 132, 242)).

451. LaMont does not know whether GDU on its own at its dose would eliminate tumors. (R22 (LaMont, Dep. at 74-75)).

Response to Finding No. 451

Based on the available data, Dr. LaMont expressed the following opinion: "There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains turmeric, feverfew and quercetin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents." R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

452. LaMont recommends curcumin to inhibit inflammation. (R22 (LaMont, Dep. at 27)).

Response to Finding No. 452

Respondents concur.

453. LaMont recommends that her patients use turmeric in their diet and have them supplement it in a dose of around 300 milligrams a day. (R22 (LaMont, Dep. at 27)).

Response to Finding No. 453

Respondents have no specific response.

454. LaMont's understanding is that 300 milligrams of turmeric per day has been commonly found to be effective at reducing inflammation. (R22 (LaMont, Dep. at 28)).

Response to Finding No. 454

Respondents have no specific response.

455. LaMont thinks that taking turmeric in high doses can inhibit clot formation. (R22 (LaMont, Dep. at 30-31)).

Response to Finding No. 455

Respondents have no specific response.

456. One clinical study that LaMont can mention came out last month and involved the use of turmeric or curcumin in patients with pancreatic cancer. (R22 (LaMont, Dep. at 38-39)).

Response to Finding No. 456

Respondents have no specific response.

457. According to LaMont, the 2008 study involving patients with pancreatic cancer used eight grams of a curcuminoid a day. (R22 (LaMont, Dep. at 38-39)).

Response to Finding No. 457

Respondents have no specific response.

458. LaMont believes that GDU contains 300 milligrams of turmeric. (R22 (LaMont, Dep. at 40)).

Response to Finding No. 458

Respondents have no specific response.

459. LaMont does not know whether 300 milligrams of turmeric were also studied in the context of the 2008 study. (R22 (LaMont, Dep. at 41)).

Response to Finding No. 459

Respondents have no specific response.

460. LaMont is not familiar with any clinical studies of curcumin at 300 milligrams per day. (R22 (LaMont, Dep. at 41-42)).

Response to Finding No. 460

Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. *FTC, Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

461. LaMont has “no way of knowing how many milligrams [of quercetin] would produce a certain therapeutic response.” (R22 (LaMont, Dep. at 64)).

Response to Finding No. 461

Respondents have no specific response.

462. LaMont agreed that the dosage found in GDU is on the lower end of the therapeutic spectrum. (R22 (LaMont, Dep. at 67)).

Response to Finding No. 462

Based on the available data, Dr. LaMont expressed the following opinion: “There

is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains turmeric, feverfew and quercetin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents” R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

463. LaMont agrees that there is a big difference between seeing bromelain work in the capacity of a swollen ankle and having it work in the context of cancer. (R22 (LaMont, Dep. at 71-72)).

Response to Finding No. 463

Respondents have no specific response.

464. LaMont does not know what dosage of feverfew was contained or used in the study from Molecular Cancer Therapies in April 2005. (R22 (LaMont, Dep. at 80)).

Response to Finding No. 464

Respondents have no specific response.

465. LaMont does not know what dosage of feverfew was used in the study from the British Journal of Pharmacology in 2002. (R22 (LaMont, Dep. at 81)).

Response to Finding No. 465

Respondents have no specific response.

BioMixx

James Duke, Ph.D.

466. Duke does not know how much of the elements that are in BioMixx are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 534).

Response to Finding No. 466

Dr. Duke was offered as an expert to testify regarding the components of the DCO products and their effects on the human body, and not to testify about the formulation of the products themselves (R 3 (Expert Witness Report of James Duke, Ph.D. at 13)). Based on the data available, Dr. Duke expressed the following opinion: “There is a reasonable basis for the claims that the ingredients of BioMixx, ‘boosts the immune system ... to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments.’” (R 3 (Duke, Expert Witness Report, at 13)).

Sally B. LaMont, N.D.

467. LaMont recognizes that BioMixx “certainly has not gone through those kind of clinical trials that would prove that it’s going to cure cancer.” (R22 (LaMont, Dep. at 172)).

Response to Finding No. 467

Respondents do not claim that BioMixx cures cancer (Complaint, Exhibits A-D), and Respondents need only substantiate the claims they do make. Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary

supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

468. LaMont “do[es]n’t think as a stand-alone [product] BioMixx is going to cure their cancer or probably even effectively treat it.” (R22 (LaMont, Dep. at 176)).

Response to Finding No. 468

Respondents do not claim that BioMixx cures or effectively treats cancer (Complaint, Exhibits A-D), and Respondents need only substantiate the claims they do make. Clinical trials are not required for dietary supplements. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), (“Placebo-controlled, double-blind testing is not a legal requirement for consumer products.”). There is no fixed formula for the type of studies required for establishing a reasonable basis for claims relating to dietary supplements. FTC, *Dietary Supplements: An Advertising Guide for Industry* at 5 (2001).

469. LaMont did not write that BioMixx is effective in the treatment of cancer in her report. (R22 (LaMont, Dep. at 210)).

Response to Finding No. 469

Respondents do not claim that BioMixx treats, cures, or prevents cancer (Complaint, Exhibits A-D), and Respondents need only substantiate the claims they do make. Based on the available data, Dr. Lamont expressed the following opinion: “There is a reasonable basis to claim that that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer,

cachexia and in healing the destructive effects of radiation and chemotherapy treatments.” R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

470. LaMont is not concluding that BioMixx is effective in the treatment of cancer. (R22 (LaMont, Dep. at 211)).

Response to Finding No. 470

Respondents do not claim that BioMixx is effective in the treatment of cancer (Complaint, Exhibits A-D), and Respondents need only substantiate the claims they do make. Based on the available data, Dr. Lamont expressed the following opinion: “There is a reasonable basis to claim that that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments” R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

471. LaMont is not concluding that BioMixx completely heals the destructive effects of radiation and chemotherapy. (R22 (LaMont, Dep. at 211)).

Response to Finding No. 471

Based on the available data, Dr. Lamont expressed the following opinion: “There is a reasonable basis to claim that that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments.” R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

472. LaMont does not know whether BioMixx is effective in the prevention, treatment, or cure of cancer. (LaMont, Tr. 580-81).

Response to Finding No. 472

Respondents do not claim that BioMixx is effective in the prevention, treatment or cure of cancer (Complaint, Exhibits A-D), and they need only substantiate the claims they do make. Based on the available data, Dr. Lamont expressed the following opinion: “There is a reasonable basis to claim that that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments.” R 4 (Expert Witness Report of Sally LaMont, N.D. at 40).

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

**In the Matter of
DANIEL CHAPTER ONE,
a corporation, and

JAMES FEIJO,
Individually, and as an officer of
Daniel Chapter One.**

DOCKET NO. 9329

PUBLIC DOCUMENT

RESPONDENTS' POST-HEARING REPLY BRIEF

I. INTRODUCTION

The hearing evidence demonstrates that Respondents Daniel Chapter One ("DCO") and James Feijo, its Overseer, complied with Sections 5(a) and 12 of the Federal Trade Commission Act (the "FTC Act") when presenting their Bio* Shark, 7 Herb Formula, GDU, and BioMixx products (collectively, the "DCO Products") to interested members of the public. Respondents presented information disseminated on the Internet, on the radio, and in written material that was supported by competent and reliable scientific evidence. They said specifically that the DCO Products contained components that could strengthen the immune system, reduce inflammation, promote cell repair, relieve pain and have other effects on the structure or function of the body which reinforce its innate capacity to maintain well being, including, as examples, resisting diseases and conditions such as cancer or tumors.

Specifically Respondents said about the DCO Products:

- "Bioshark is 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 . . ."

- Seven Herb Formula "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"
- GDU "contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."
- BioMixx"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

In its complaint, the Federal Trade Commission transformed the structure and function statements made by Respondents into what Complaint Counsel characterized as "heath and disease claims" that Respondents did not make and deny making.

Specifically the FTC asserts that Respondents made the following statements:

- a. Bio*Shark inhibits tumor growth;
- b. Bio*Shark is effective in the treatment of cancer;
- c. 7 Herb Formula is effective in the treatment or cure of cancer;
- d. 7 Herb Formula inhibits tumor formation;
- e. GDU eliminates tumors;
- f. GDU is effective in the treatment of cancer;
- g. BioMixx is effective in the treatment of cancer; and
- h. Bio Mixx heals the destructive effects of radiation and chemotherapy.

The following chart places the two sets of statements side by side for comparison:

Claims Comparison Chart

The FTC's attribution to DCO	DCO's actual claim
<p><u>About Bioshark:</u></p> <p><i>"Bioshark inhibits tumor growth"</i></p> <p><i>"Bioshark is effective in the treatment of cancer"</i></p>	<p><i>"Bioshark is 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 . . ."</i></p>

<p><u>About 7 Herb Formula:</u></p> <p><i>"7 Herb Formula is effective in treating and curing cancer"</i></p> <p><i>"7 Herb Formula inhibits tumor formation"</i></p>	<p><i>"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"</i></p>
<p><u>About GDU:</u></p> <p><i>"GDU eliminates tumors"</i></p>	<p><i>"contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. ."</i></p>
<p><u>About BioMixx:</u></p> <p><i>"BioMixx is effective in the treatment of cancer"</i></p> <p><i>"BioMixx heals the destructive effects of radiation and chemotherapy"</i></p>	<p><i>"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."</i></p>

Respondents' expert Dr. Sally LaMont, ND, reviewed the claims made by Respondents and the information provided by Respondents and concluded: "Based on my experience and expertise, as well as the research cited above, I hold the following opinions:

- "A. There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains turmeric,

feverfew and quercetin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents.

“B. There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.

“C. There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments.

“D. There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis - the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.”

Respondents' expert Dr. James Duke, PhD, made the following findings:

“Reviewing the MAM's and the IE's¹ for the constituents of the DCO products in the manner that I have reviewed thousands of uses for hundreds of herbs for several decades, it is clear that significant evidence in support of the following uses exists:

“There is a reasonable basis for the claims that the ingredients of 7 Herb Formula, ‘... , fights tumor formation, and fights pathogenic bacteria.’

¹ MAM'a and IE'S are measures of information developed by Dr. Duke to evaluate herbs. (Duke Report)

“There is a reasonable basis for the claims that the ingredients of GDU, ‘contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein --even that of unwanted tumors and cysts. This formula also contains ingredients known to help relieve pain and heal inflammation. GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . .’

“There is a reasonable basis for the claims that the ingredients of BioMixx, ‘boosts the immune system, ...to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments.’”

Respondents made permissible claims about the effects of their supplements on the structure and function of the body based on factual information in their possession, thereby complying with section 5 and 12 of the Federal Trade Commission Act.

II. STATEMENT OF FACTS ABOUT RESPONDENTS’ MESSAGE

A. As Part Of Their Religious Ministry Respondents Provided Dietary Supplements To Their Followers, Associates and Other Individuals Who Sought Natural Alternative and Complementary Adjuncts To Chemotherapy, Radiation and Surgery.

Daniel Chapter One began as a ministry in 1983, first as a street ministry and then as a ministry to help home churches in Communist countries (where church activities conducted in Christian practitioners’ homes were discouraged, if not illegal).

(Respondents’ Reply to Complaint Counsel’s Proposed Finding of Fact 6, hereinafter RRCCPF 6)

DCO did not act as a business engaged in the “sale, retail, wholesale, and distribution of health products.” It was in fact a house ministry, a home church, and a home fellowship. These ministry activities were based on Biblical principles and were designed to fulfill the spiritual needs of the ministry’s constituents. These activities included: holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, and conducting healings.

Between 1990 and 1997 annual for-profit corporation reports, of which Overseer Feijo has only a vague recollection, were filed on behalf of a corporation with the name Daniel Chapter One, Inc. with the state of Rhode Island. During that time Daniel Chapter One, Inc.’s corporate status was repeatedly revoked, and for significant periods of time between 1991 and 1997 Daniel Chapter One, Inc. was not recognized by Rhode Island as a corporation in good standing. Respondent James Feijo never intended for DCO to be a for-profit corporation. The Challenged Products were created after Daniel Chapter One, Inc.’s corporate status was revoked. (RRCCPF 16)

Until 2002 DCO was an unincorporated religious association and in 2002 it was recognized by the State of Washington as a religious Corporation Sole. Throughout its entire existence, James Feijo has overseen DCO as a non profit religious ministry. DCO has frequently given away its products free of charge, does not now and never has made a profit from any of its activities, including providing information through print or through its website, or from its radio show (RRCCPF 17)

B. Respondents Are Responsible For the Development of the Message of Their Ministry Including, Print, Broadcast and Internet Information, Presentations at DCO Followers Meetings and Dietary Supplement Formulas and Labels

**1. Respondent James Feijo Arranged For The Development—
Through Technical Consultants And Advisors—Of DCO
Products, Labels, And Informational Material**

Respondents have obtained the services of professionals to prepare the labels, develop the formula for 7 Herb Formula, and manufacture their products. They work in conjunction with these professionals to create the products. They are solely responsible for the content of the messages they include in their spiritual /religious undertakings.

**2. Respondents are Engaged In Commerce, If At All, Incidentally To
and As A Part of Their Spiritual/Religious Mission**

Respondents do not advertise DCO dietary supplements. The information about the DCO products occurs as an integral part of DCO's spiritual/religious message about the natural power of the body to heal itself with the help of God. Evidence shows that most of the viewers and users of DCO's website are followers of DCO's ministry who visit DCO's website to obtain more information about DCO's products. Respondent DCO has no advertising budget. Respondents do not advertise for their products through the BioGuide, the Cancer Newsletter, or the Most Simple Guide. The BioGuide was intended for sharing the Feijos' own religious testimony, and quotes verses from the Bible. The Cancer Newsletter, a one-time brochure reprinted once with minor updates, was intended for sharing testimony from users of DCO's products. The Most Simple Guide was originally created for doctors at those doctors' request for information on the DCO products that people have found to be helpful. (RRCCPFs 28 and 134)

DCO's website, BioGuide, and Respondents' radio show are intended to provide information about Respondents' perspectives on spiritual and physical well-being, and not for the purpose of promoting DCO's products. DCO's website enables the followers of Respondents' ministry to obtain DCO's products, and such followers would

understand that the money they send in is a donation in support of the ministry. The BioGuide was intended for sharing the Feijos' own religious testimony, and quotes verses from the Bible. The radio show enables followers of Respondents' ministry to discuss their physical and spiritual well-being and to learn about non-drug approaches to balancing the body, mind, and spirit, including the use of dietary supplements to support their well-being, and is not intended for the purpose of promoting DCO's products.

(RRCCPF 29)

C. Respondents Disseminate Claims That the DCO Products "Fight Cancer," "Stop Tumor Growth," And Are a "Cancer Solution" For All Types Of Cancer, None of Which Is a Claim to Cure, Treat Or Prevent Cancer, But All Of Which Are Structure and Function Claims For Alternative And Complementary Adjuncts To Conventional Treatment

Respondents do not claim that their products cure, mitigate, or prevent (the Complaint, at paragraph 5, does not even allege that the products claim to mitigate,) cancer or tumors (nor are tumors a disease or even necessarily cancerous). Respondents set forth the permissible structure/function claims that have been made, along with the expert opinions that the science supports these claims, in the Introduction section of this brief. (RRCCPF 134)

The statements from DCO's website, as cited, indicate that these products are "supporting products" that can be used in conjunction with cancer treatments, whatever those may be. The cited statements clearly do not claim that the DCO products can cure, treat, or prevent cancer. In fact they say "Supporting Products...Daniel Chapter One advises to get familiar with the supporting products below: CANCER TREATMENT:"

This is a straight forward claim that the product will “support” cancer treatment whatever it might be. (RRCCPF 137)

The intended and most frequent audience of the DCO web pages are followers of the DCO ministry, which advocates, based on Biblical text and teachings, that only God can cure disease and that nature provides the best approach to helping the body balance itself. DCO’s website states: “The information on this website is intended to provide record and testimony about God and His creation. It is not intended to diagnose a disease.” Followers of the DCO ministry understand the wording on this page in light of the basic tenet of the religion, namely that DCO products use natural substances provided by God to treat imbalances within the body, and that these products can support whichever type of cancer treatment one decides to pursue. (RRCCPF 137)

Respondents note that there is no claim that the products cure, treat, or prevent cancer or tumors in the statements cited by Complaint Counsel. Respondents do not believe that its agents or any other agents can cure, treat, or prevent cancer, and therefore did not claim that they could. Respondents believe that the word “disease” in general, and words describing specific “diseases” in particular, are ways to linguistically refer to imbalances in the body that only God, working through the body’s own innate healing capacity, and with the help of substances He created in nature for humankind’s use, can restore. (RRCCPF 138)

1. Claims That The DCO Products Are For All Types Of Cancer Are Consistent With Respondents’ Assertion That They Offer Their Supplements As Adjuncts To Any Chosen Approaches To Balancing the Body

Complaint Counsel says, “Respondents recommend taking the DCO Products ‘If you suffer from any type of cancer,’ CCPF 153,157,166, and 171 (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.'

Respondents reinforce this claim by listing at least ten different types of cancer with consumer 'testimonials.'" (CCPF 139). None of the statements attributed to Respondents in this paragraph is a claim to cure, treat or prevent cancer. All are consistent with Respondents' intention to provide supplements that support whatever treatment choice is being followed. It is comparable to—in fact, since the substances at issue are food supplements, it is almost the same as—saying that if you have cancer eating a good diet will help you fight it.

2. Claims That The DCO Products Will Fight Cancer Are Consistent With Respondents' Assertion That They Offer Their Supplements As Adjuncts To Any Chosen Approach To Balancing the Body

Complaint Counsel cites two testimonials that make Respondents' point.

The author of the first testimonial states, "When I decided not to do chemotherapy or radiation...", thus indicating that the testifier chose the DCO products **after** deciding to forego chemotherapy. Respondents also note that the testifier did not discover the DCO products through the website or the radio program but rather received them from her father. The cited testimonial is consistent with DCO's assertion that its products are intended to be and are a good support for whichever approach one chooses for one's physical imbalances that leads to conditions, named "diseases" by conventional medicine. In the context of their religious philosophy, Respondents view such conditions as internal spiritual and bodily imbalances. (RRCCPF 140)

Complaint Counsel quotes the second testimonial, saying, "In Respondents'

BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents

published the following testimonial from Buzz McKay: ‘I had beam radiation for *prostate cancer*. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later, it was down to 0.16! 7 Herb Formula is extremely well done - fantastic. I still take 2 ounces of *7 Herb Formula* every morning; I plan to stay on that forever! *I figure 6 ounces (2 morning, 2 afternoon, 2 evening) did such a good job fighting cancer*, 2 ounces is a good prophylaxis!’” Once again this testimonial is completely consistent with and supports Respondent’s assertion that it presents, and intends for its supplements to be used as an adjunct to treatment that help strengthen the structure and function of the body whatever treatment might be chosen. (RRCCPF 160)

The evidence on claims put forward by Complaint Counsel refutes the assertion that Respondents intend their supplements to cure, treat and/or prevent cancer and supports the Respondents’ assertion that they intend their supplements to strengthen the innate balancing structure and functions of the body to help it fight for, create, and enhance balance. Respondents’ experts say the relevant science supports these claims.

3. Claims That The DCO Products Will Fight And Stop Tumors are Consistent With Respondents’ Assertion That They Offer Their Supplements as Adjuncts to Any Chosen Approach To Balancing the Body

Complaint Counsel says Respondents claim that the Challenged Products “...Helps to relieve pain, inflammation, and as *an adjunct to cancer therapy*.” CCPF 1167 (emphasis added). This is precisely Respondents’ point. They offer a message that says God created humans with an innate ability to heal themselves, and that by embracing God’s message (such as the nutritional information contained in the Book of Daniel

Chapter One and other parts of the Bible) and by using natural herbal supplements **as an adjunct to cancer therapy**, cancer can successfully be fought.

This message, which is both scientific and spiritual, is the opposite of the assertion that any product—drug, supplement, food, device or other—can cure, treat, or prevent cancer. Respondents do not believe that any product, including the supplements they provide, can cure, treat or prevent any “disease.” Or even, alone, correct an imbalance in the body. Their message is clear about this belief. They believe and assert, and their claims are limited to stating, that the supplements they provide work as an adjunct to all the other undertakings that must be engaged in when the imbalance of disease undermines people. To say that the message Respondents delivers is that their supplements cure, treat, or prevent any disease, let alone cancer, against their religious belief, defies the herbal science that supports their statements and is untrue.

III. THE FTC IS VIOLATING RESPONDENTS’ FIRST AMENDMENT RIGHTS.

A. Complaint Counsel Has Ignored Respondents’ First Amendment Claim That Their Marketing Solicitations Are an Integral Part of an Overall Religious and Political Ministry

In his Post-Trial Brief, Complaint Counsel persists in misstating Respondent’s First Amendment claim that their speech deserves the highest protection, namely that afforded to political speech. Complaint Counsel asserts that “Respondents have argued that their **advertising representations** are constitutionally protected religious and political speech that is immune to the FTC Act’s prohibition against unfair and deceptive practices.” *See* Complaint Counsel’s Post Trial Brief, p. 32 (emphasis added). That is not Respondents’ argument. Rather, Respondents have maintained that their “promotional materials related to Daniel Chapter One’s products **cannot** be isolated from

their overall religious ministry of health freedom and healing, [but] are an integral part of [DCO's] informational campaign to educate the public on nutrition, herbal, and other dietary alternatives to the pharmaceutical-drug-based medical care system endorsed and sustained by the Food and Drug Administration and other governmental agencies.”

Respondent's Motion to Dismiss and Supporting Memorandum of Points and Authorities, pp. 13-14 (Jan. 13, 2009) (emphasis added). Thus, Complaint Counsel is mistaken in its attempt to isolate Respondents' promotional statements about their products, as if they stand apart from Respondents' overall religious and political mission.

Complaint Counsel's insistence that DCO's product marketing statements be isolated from DCO's overall religious and political mission as unprotected commercial speech is comparable to the efforts by other government agencies to isolate an organization's charitable solicitations which are integral to that organization's political mission. The Supreme Court has resoundingly rejected that approach:

Soliciting financial support is undoubtedly subject to reasonable regulation but the latter must be undertaken with due regard for the reality that solicitation is characteristically intertwined with informative and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political or social issues, and for the reality that without solicitation the flow of such information and advocacy would likely cease. [*Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 632 (1980).]

It is Respondents' contention in this case that the First Amendment rule that applies to charitable solicitations applies to DCO's marketing statements because the latter, like the former, are an integral part of the overall religious and political ministry of Respondents. In their January 13 motion to dismiss on First Amendment grounds, Respondents relied upon *New York Times v. Sullivan*, 376 U.S. 254 (1964) for the proposition that the First Amendment protected all of Respondents' statements in

furtherance of their religious mission, unless the FTC could show them to be knowingly false or made in reckless disregard of their truth of falsity. Respondents' Motion to Dismiss, pp. 13-15. That same standard has been embraced by the Supreme Court in its latest charitable solicitation case in order to "provide sufficient breathing room for protected speech." *Illinois ex rel Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 620-21 (2003). For the reasons stated in their January Motion to Dismiss, the *New York Times v. Sullivan* "actual malice" standard applies here.

B. Even if Afforded Only the Constitutional Protection Provided for Commercial Speech, Complaint Counsel Has Not Met His Burden of Proof that Such Speech is Not Protected by the First Amendment

In his Post Trial Brief, Complaint Counsel persists in erroneously assuming that Respondents' promotional statements are *per se* misleading. Complaint Counsel Post Trial Brief, pp. 33-35. As pointed out in Respondents' Post Trial Brief, however, Complaint Counsel has not met his burden of proving that Respondents' statements are misleading. See Respondents' Proposed Finding of Fact, Conclusions of Law and Order, and Brief in Support Thereof, pp. 16-22. Even if Complaint Counsel could show that Respondents' promotional statements are "likely to mislead," Complaint Counsel has failed to meet his burden that the FTC's censorship of such claims is a direct and necessary means to achieve a substantial government interest, as required by the Supreme Court's commercial speech doctrine. *Pearson v. Shalala*, 163 F.3d 650, 655 (D.C. Cir. 1999); Respondents' Post Trial Brief, pp. 22-24.

C. Complaint Counsel Has Erroneously Assumed that the First Amendment's "Prior Restraint" Doctrine Applies Only to Laws Requiring a Government License to Publish in the First Instance

According to Complaint Counsel, Respondents' objection to these administrative proceedings as an unconstitutional prior restraint must be dismissed solely on the ground that "[t]here has been no prior restriction on Respondents' advertisements" and that "Respondents are in no way compelled to discontinue claims in already-disseminated advertisements that they believe to be truthful until the FTC has proven that the claims are deceptive and a final order is issued prohibiting the claims." Complaint Counsel's Post Trial Brief, p. 35. In short, Complaint Counsel insists that the order that it seeks to enjoin **future** promotional statements is not subject to the Supreme Court's prior restraint doctrine because the FTC did not require Respondents to obtain a license **before** they made the promotional statements at issue in this case. In *New York Times v. United States*, 403 U.S. 713 (1971), there was no law that required the *New York Times* or the *Washington Post* to obtain a license **before** publishing the Pentagon Papers. Rather, after the publication of those papers the government sought a court order to enjoin the two newspapers from further publication of those papers and related materials. In a *per curiam* opinion, the Supreme Court did not hesitate to invoke its First Amendment doctrine of "prior restraint," placing a "heavy presumption against [the] constitutional validity" of a judicial restraint against such future publication. *New York Times v. United States*, 403 U.S. at 714.

That heavy presumption of unconstitutionality applies equally to the FTC and any other administrative agency empowered by Congress to enjoin the future publication of allegedly "deceptive" statements. Indeed, if State and Defense Department's appeal to "national security" was found constitutionally insufficient — as the Court did in the Pentagon Papers case — the FTC's appeal to the need for "competent and reliable

scientific evidence” in this case is clearly insufficient. As Justice Brennan observed in the Pentagon Papers case, the First Amendment prohibits a court injunction based upon “surmise or conjecture that untoward consequences may result.” *Id.*, 403 U.S. at 725-26. The First Amendment doctrine of prior restraint would also prohibit an FTC order enjoining Respondents when that order is based upon the FTC’s “overall net impression” that Respondents’ promotional statements are misleading without any concrete evidence that anyone was misled by such statements or physically harmed.

D. Complaint Counsel Erroneously Assumed that Respondents’ First Amendment Religion Claim is Based Solely Upon Religious Conscience

Complaint Counsel cavalierly dismisses Respondents’ religious freedom claims on the sole ground that “Respondents[’] religious motivation in making the claims [about their products] is irrelevant.” *See* Complaint Counsel’s Post Trial Brief, p. 35. At no time have Respondents based any First Amendment religion claim on a **subjective** “religious motivation” or religious conscience. To the contrary, Respondents’ free exercise and establishment clause claims have always been based upon the **objective** standard that it is outside the FTC’s jurisdiction to interdict Respondents’ product claims on the sole ground that those claims were not based upon “competent and reliable scientific evidence.” *See* Respondents’ Motion to Dismiss, pp.17-18.

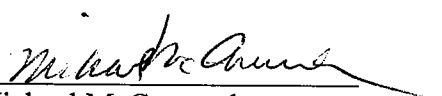
On the one hand, the FTC’s attempt to override Respondents’ testimonial approach to the efficacy of their products is a violation of Respondents’ free exercise of religion, an intrusion forbidden by *United States v. Ballard*, 322 U.S. 78 (1944). Respondents’ Motion to Dismiss, pp. 17-20. On the other hand, the FTC’s attempt to impose its “scientific orthodoxy” upon Respondents constitutes a forbidden establishment

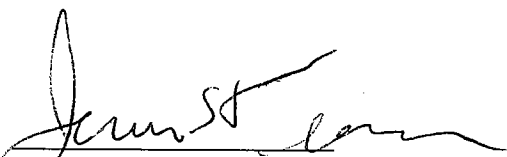
of religion, namely, the religion of “scientism.” Respondents’ Motion to Dismiss, p. 20. Complaint Counsel addresses neither of these claims in his Post Trial Brief. Rather, he sets up a straw man relegating Respondents’ objectively-based claims as if they are appeals based upon Respondents’ “subjective intent.” See Complaint Counsel’s Post Trial Brief, pp. 35-36.

While the FTC may have no qualms about enforcing its orthodoxy of double-blind, placebo-based tests upon Respondents, the First Amendment religion guarantees forbids the government from imposing upon the American people any such form of orthodoxy — in the name of “science” or in any government-approved belief system. *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943). After all, it is one thing for the FTC to enjoin a person from making false scientific claims for their products, but it is quite another thing to enjoin a person from making truthful claims that the FTC finds to be “deceptive” because those claims do not conform to the FTC’s established scientific world view.

Dated: June 11, 2009

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CERTIFICATE OF SERVICE

I certify that on June 11, 2009, I filed, served or caused to be served or filed, the following documents on the individuals listed below as noted:

Respondents' Reply to Complaint Counsel's Proposed Findings of Fact and Brief in Support Thereof

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

Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-135
Washington, DC 20580
Email: secretary@ftc.gov

One paper copy via Federal Express (for delivery on June 12, 2009) and one electronic copy to each to:


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Four paper copies via hand delivery and one electronic copy to:

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