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

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

COMPLAINT COUNSEL'S COUNTER-STATEMENT OF MATERIAL FACTS IN RESPONSE TO RESPONDENTS' STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF MOTION FOR SUMMARY DECISION

Pursuant to Commission Rule of Practice 3.24, 16 C.F.R. § 3.24, and in support of the *Opposition* to Respondents' *Motion for Summary Decision*, Complaint Counsel submit this *Counter-Statement of Material Facts*, addressing Respondents' Statement of Undisputed Facts. ¹ The statements below are numbered to correspond to Respondents' statements. ²

As a threshold matter, Complaint Counsel generally dispute Respondents' characterization of their "undisputed facts." Most of the matters presented are not material to the

¹ Respondents did not submit their "Statement of Undisputed Facts" by the February 24, 2009 deadline established by this Court for motions for summary decision. As explained more fully in Complaint Counsel's Opposition to Respondents' "Request for Leave to Amend Respondents' Motion for Summary Decision" (and incorporated herein by reference), Respondents' submission of their "Statement of Undisputed Facts" is untimely and not supported by any evidence in the record, and, therefore, should be stricken.

² The evidence and facts pertinent to the issues in this case are fully set forth in Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Issue, Exhibits Submitted in Support of Complaint Counsel's Motion for Summary Decision (Volumes I and II), and Deposition Testimony Submitted in Support of Complaint Counsel's Motion for Summary Decision, accompanying Complaint Counsel's Motion for Summary Decision.

issues before the Court, and Respondents provide no citations to any evidence in the record supporting their "undisputed facts." Many of Respondents' statements are incomplete or lacking context and hence mischaracterize the "facts" they purport to state.

Therefore, Complaint Counsel submit the following Counter-Statement, demonstrating that there are no genuine issues for trial and that Respondents' Motion for Summary Decision should be denied and that Complaint Counsel's Motion for Summary Decision should be granted:

- 1. Complaint Counsel do not dispute that Daniel Chapter One (DCO) was "formed as a Corporation Sole in Washington State." This fact, however, is irrelevant and immaterial to any viable legal defense presented in Respondents' Motion for Summary Decision.
- 2. Because Respondents do not provide any documents or citations as to the source of this allegedly "undisputed fact," Complaint Counsel cannot verify the accuracy of the following statement:

Welcome to Daniel Chapter One Online!

Daniel Chapter One got its name from the Old Testament, book of Daniel, first chapter. In that account, Daniel and his men were being held in Babylonian captivity, and were expected to eat the king's food - so as to be fit and strong servants.

But Daniel asked permission to eat a vegetable diet and to drink only water, rather than partake of the rich meats and wine of the king. The king's men said no; surely Daniel would get sick, maybe die! So Daniel asked for a trial of 10 days. At the end of Chapter One, it is recorded that Daniel and men, after that trial, were strong in flesh, with bright eyes, and continued to grow in knowledge and wisdom.

So it was that the founders of Daniel Chapter One®, since trying their own "Daniel Chapter One" diet for 10 days and discovering that indeed they felt fantastic, decided to name the health food store they began, after that portion of the bible. The company, then and now, does not push a vegetarian diet for wellness, but simply a healthy diet of wholesome, natural foods - rather than the unwholesome, artificial food of the modern world. It's about eating with purpose, and partaking of the good food God has given us for health and healing. Good food for physical, mental, and emotional health includes herbs and nutrients.

The tiny health food supplement store Daniel Chapter One® grew and grew, from one to several locations. As the store grew, so the founders grew - in knowledge and wisdom,

as in fact Daniel had experienced! The store quickly became more of a natural healing center. From their hands-on expertise, the couple began next to design the nutritional supplement product line now known world over as Daniel Chapter One.

To the extent Respondents' statement accurately reflects what appears on the DCO Web site, Complaint Counsel do not dispute this fact. This fact, however, is irrelevant and immaterial to any viable legal defense in Respondents' Motion for Summary Decision.

3. Because Respondents do not provide any documents or citations as to the source of this allegedly "undisputed fact," Complaint Counsel cannot verify the accuracy of the following statement:

The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or supplements should not be mixed with certain medications.

To the extent Respondents' statement accurately reflects what appears on the DCO Web site, Complaint Counsel do not dispute this fact. This fact, however, is irrelevant and immaterial to any viable legal defense in Respondents' Motion for Summary Decision.

- 4. Complaint Counsel dispute Respondents' unsupported assertion that "DCO states on its website the following statement in regard to each of the Challenged Products: "*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." For example, this statement does not appear on the Web pages contained in Complaint Counsel's Summary Decision Exhibit (hereinafter referred to as "S.D. Ex. ____") 7 (submitted to the Court on February 24, 2009). See Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Issue (hereinafter referred to as "CCSF") ¶ 104 (citing S.D. Ex. 7-8) (submitted to the Court on February 24, 2009). To the extent Respondents' statement accurately reflects what appears elsewhere on the DCO Web site, Complaint Counsel do not dispute this fact. This fact, however, is irrelevant and immaterial to any viable legal defense in Respondents' Motion for Summary Decision.
- 5. Complaint Counsel do not dispute this fact. See CCSF ¶ 119.
- 6. Complaint Counsel do not dispute this fact. See CCSF ¶ 124.
- 7. Complaint Counsel do not dispute this fact. See CCSF ¶ 132.
- 8. Complaint Counsel do not dispute this fact. See CCSF ¶ 137.
- 9. In their Answer, Respondents admit making these representations regarding Bio*Shark. See also CCSF ¶ 122 (stating "Bio*Shark Shark Cartilage Stops tumor growth in its

- tracks"); CCSF ¶ 120 (stating "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: . . . Bio*Shark™"). Whether Respondents expressly made these specific statements, however, is not material. Rather, the fact that Respondents made these representations regarding Bio*Shark contributes to the overall net impressions created by the challenged advertising.
- 10. In their Answer, Respondents admit making these representations regarding 7 Herb Formula. See also CCSF ¶ 125 (stating "7 Herb Formula battles cancer"); CCSF ¶ 128 ("[w]ith Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors"). Whether Respondents expressly made these specific statements, however, is not material. Rather, the fact that Respondents made these representations regarding 7 Herb Formula contributes to the overall net impressions created by the challenged advertising.
- 11. In their Answer, Respondents admit making the representations regarding GDU. See also CCSF ¶ 132 (stating that GDU "[c]ontains natural proteolytic enzymes . . . 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"); CCSF ¶ 133 (stating "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: . . . GDU CapsTM"). Whether Respondents expressly made these specific statements, however, is not material. Rather, the fact that Respondents made these representations regarding GDU contributes to the overall net impressions created by the challenged advertising.
- 12. In their Answer, Respondents admit making these representations regarding BioMixx. See also CCSF ¶ 137 (stating that "Bio*Mixx... is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments"); CCSF ¶ 138 (stating "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: ... BioMixxTM"). Whether Respondents expressly made these specific statements, however, is not material. Rather, the fact that Respondents made these representations regarding BioMixx contributes to the overall net impressions created by the challenged advertising.
- 13. Complaint Counsel do not dispute that "[t]he Commission has no factual extrinsic evidence that DCO [sic] alleged practices caused substantial injury to consumers." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 14. Complaint Counsel do not dispute that "[t]he Commission has no factual extrinsic evidence that DCO [sic] alleged practices are likely to cause substantial injury to consumers," although Denis R. Miller, M.D. concluded that "complementary medicine should and does not serve as an alternative to effective and safe anticancer therapy. Suggesting that it can be an effective substitute for traditional medicine would be a disservice to cancer patients. Delays in effective therapy may allow cancer cells to regrow, develop resistance to therapy, and metastasize." S.D. Ex. 1 at 11. At his

deposition, Dr. Miller also testified about the potential harm to cancer patients who use complementary medicine as a substitute for traditional medicine. *See generally* Deposition Transcript of Denis R. Miller, M.D. at 90, 122, and 176 (submitted to the Court on February 24, 2009). Furthermore, Respondents' expert, Sally LaMont, N.D., testified that there is a danger if consumers do not continue with traditional cancer therapy and stated that there always is a danger that people will take DCO products and not go and see their physicians. CCSF ¶¶ 361, 363. Respondents' "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.

- 15. Complaint Counsel do not dispute that "[t]he Commission has no factual extrinsic evidence that DCO [sic] alleged practices cannot be reasonably avoided by consumers." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 16. Complaint Counsel do not dispute that "[t]he Commission has no factual extrinsic evidence that DCO [sic] alleged practices are not outweighed by countervailing benefits to consumers." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 17. Complaint Counsel do not dispute that "[t]he Commission has no factual extrinsic evidence that DCO [sic] alleged practices are not outweighed by countervailing benefits to competition." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 18. Complaint Counsel do not dispute that "[t]he Commission has no factual evidence of consumer perceptions about DCO, its products or its claims, either express or implied." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 19. Complaint Counsel do not dispute that "[t]he Commission has no factual evidence of consumer expectations about DCO, its products or claims, either express or implied." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 20. Complaint Counsel do not dispute that "[t]he Commission has no factual evidence about the cost of developing substantiation for DCO's express claims." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.
- 21. Complaint Counsel do not dispute that "[t]he Commission has no factual evidence about the amount of substantiation experts in the field of dietary supplements believe is reasonable for structure/function claims about those supplements." This "undisputed fact," however, is not material to a finding that Respondents engaged in deceptive, unsubstantiated advertising.

- 22. Complaint Counsel dispute Respondents' unsupported assertion that "[t]he Commission has no factual evidence concerning whether the express statements made by DCO as described in ¶¶ 5-8 above are false, misleading, unfair, or deceptive," as it is a mischaracterization of the record. The uncontroverted evidence shows that Respondents conducted no scientific testing on Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively referred to as the "DCO Products"), have not conducted any double-blind studies on the DCO Products, and have not conducted any controlled studies on any of the DCO Products. CCSF ¶¶ 149-151, 159, 166-68. Respondents have not engaged any others to conduct scientific tests on any of the DCO Products. ¶¶ 152, 162, 163, 169, 171. It was not Respondents' practice to obtain scientific studies about any of the components in their products. CCSF ¶ 154. Moreover, none of the five witnesses Respondents proposed as experts knows of, or has conducted, any scientific studies on the DCO Products. CCSF ¶¶ 250-51, 263, 267, 299-300, 304-05, 340-41, 368, 372, 373, 376-77, 380-81, 402-06, 415-17, 418-420, 440, 444-45, 446-49, 469-72, 473-77. Dr. Miller confirmed that there is no competent and reliable scientific evidence to substantiate the claims that the DCO Products treat, cure, or prevent cancer or tumors. CCSF ¶¶ 182-190, 195-97.
- 23. Complaint Counsel dispute Respondents' unsupported assertion that "DCO has substantiation for the express claims it made about the Challenged Products, as described in ¶ 5-8 above," as it is a mischaracterization of the record. The uncontroverted evidence shows that Respondents conducted no scientific testing on any of the DCO Products, have not conducted any double-blind studies on the DCO Products, and have not conducted any controlled studies on any of the DCO Products. CCSF ¶¶ 149-151, 159, 166-68. Respondents have not engaged any others to conduct scientific tests on any of the DCO Products. ¶¶ 152, 162, 163, 169, 171. It was not Respondents' practice to obtain scientific studies about any of the components in their products. CCSF ¶ 154. Moreover, none of the five witnesses Respondents proposed as experts knows of, or has conducted, any scientific studies on the DCO Products. CCSF ¶¶ 250-51, 263, 267, 299-300, 304-05, 340-41, 368, 372, 373, 376-77, 380-81, 402-06, 415-17, 418-420, 440, 444-45, 446-49, 469-72, 473-77. Dr. Miller confirmed that there is no competent and reliable scientific evidence to substantiate the claims that the DCO Products treat, cure, or prevent cancer or tumors. CCSF ¶¶ 182-190, 195-97.
- 24. Complaint Counsel do not dispute that Dr. Miller "did not testify about the DCO express statements described in ¶¶ 5-8 above," as Respondents' counsel never questioned him on this issue at his deposition.
- 25. Complaint Counsel dispute Respondents' unsupported assertion that "DCO's experts have given *competent* testimony that the DCO express statements described in ¶¶ 5-8 above are accurate," as it is a mischaracterization of their experts' testimony. (emphasis added). The standard is not "competent" evidence. Rather, the standard is "competent and reliable scientific" evidence. The uncontroverted evidence shows that none of the five witnesses Respondents proposed as experts knows of, or has conducted, any

scientific studies on the DCO Products. CCSF ¶¶ 250-51, 263, 267, 299-300, 304-05, 340-41, 368, 372, 373, 376-77, 380-81, 402-06, 415-17, 418-420, 440, 444-45, 446-49, 469-72, 473-77.

Respectfully submitted,

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Dated: March 10, 2009

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 10, 2009, I have filed and served the attached COMPLAINT COUNSEL'S COUNTER-STATEMENT OF MATERIAL FACTS IN RESPONSE TO RESPONDENTS' STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF MOTION FOR SUMMARY DECISION upon the following as set forth below:

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

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

Two paper copies via overnight delivery and one electronic copy via email to:

The Honorable D. Michael Chappell Administrative Law Judge 600 Pennsylvania Ave., N.W., Room H-528 Washington, DC 20580 E-mail: oalj@ftc.gov

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

James S. Turner, Esq.
Betsy Lehrfeld, Esq.
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One electronic copy via email to:

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In the Matter of

a corporation, and

Daniel Chapter One

JAMES FEIJO,

DANIEL CHAPTER ONE,

individually, and as an officer of

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

Docket No.: 9329

PUBLIC DOCUMENT

CERTIFICATE OF SERVICE

I certify that on March 10, 2009, I served or caused to be served the following document on the individuals listed below by electronic mail, followed by Federal Express delivery:

Memorandum in Opposition to Complaint Counsel's Motion for Summary Decision Respondents' Motion to Allow Additional Witnesses During Respondents' Case-in-Chief and Argument in Support

Service to:

Donald S. Clark

Office of the Secretary

Federal Trade Commission

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Washington, DC 20580

Email: secretary@ftc.gov

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Certificate of Service - 1

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