

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

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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' OPPOSITION TO COMPLAINT COUNSEL'S MOTIONS TO EXCLUDE THE TESTIMONY AND REPORTS OF RESPONDENTS' EXPERT WITNESSES DRS. JAMES DUKE, SALLY LAMONT, RUSTUM ROY, AND JAY LEHR AND MR. JAMES DEWS**

## I. INTRODUCTION

In three separate motions, Complaint Counsel seeks to block five different witnesses, proffered by Respondents as experts, from testifying in this case. This reply addresses all three motions and memoranda in support of those motions. Complaint Counsel asserts the Court should block these witnesses from testifying because their "testimony fails to meet the criteria for admissibility of expert testimony established in *Daubert.*" Respondents disagree.

Each of the five witnesses proffered by Respondents is an individual with knowledge, skill, experience, training or education required to testify as an expert on the

science of the dietary supplements that are the focus of this case. Each offers relevant and reliable opinions and testimony that Respondents assert will be useful to the Court in reaching a conclusion on the facts before it.

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Dr. James Duke is a renowned botanist who, for thirty years, worked for the US Department of Agriculture and the National Institutes of Health on the creation of natural products of various kinds from herbs. He is widely published and recognized as one of the most knowledgeable individuals in the world on the nature of herbs.

Dr. Sally LaMont is a naturopath who is trained to and does treat patients with herbs. She has acted as a policy advisor on herbal laws in California where she lives and is familiar with herbal science literature.

Dr. Rustum Roy is a world renowned materials scientist, member of the U.S. National Academy of Engineering and the Japanese, Swedish and Russian Academies of Science, founder and board chair of Friends of Health, working to apply principles of physics and engineering to health, and has conducted research on the mechanisms of homeopathy.

Dr. Jay Lehr is an expert in scientific research study design who is also familiar with Daniel Chapter One as both a user of its products and frequent and intense examiner of the principles that underlie the dietary supplements supplied by Daniel Chapter One.

Mr. Jim Dews is also a world renowned manufacturer of herbal and other health related products who advised the manufacturer of 7 Herb Formula, one of Daniel Chapter One's contested product, on how it could be formulated.

Respondents offered Dr. Roy as an expert on scientific procedures including the limitations of applying classical single chemical entity studies to complex substances

such as the herbal dietary supplements that are the subject of this hearing. Respondents proffered the other four witnesses as experts to present to the court the nature of the dietary supplement products—which are regulated differently from foods and drugs<sup>1</sup>-- that are the subject of this hearing.

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Complaint Counsel seeks to narrow the issues in the case down to the assertion that the products in question are either a drug or a food, when they are in fact dietary supplements. Complaint Counsel then seeks to exclude all expert testimony on dietary supplements as irrelevant because the products at issue are foods or drugs, and to narrow the scientific question to how drugs are tested.

Complaint Counsel's arguments against admitting the testimony and reports of the five expert witnesses proffered by Respondent are based on this strategy of narrowing the issues in the case. The arguments presented in each of the three motions and memoranda seeking exclusion of the testimony and reports of the five proffered experts are essentially identical.<sup>2</sup> These arguments are:

<sup>&</sup>lt;sup>1</sup> FDA's Guidance for Industry Substantiation for Dietary Supplement Claims Made Under Section 403(r)
(6) of the Federal Food, Drug, and Cosmetic Act says,

The Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and the legislative history accompanying DSHEA do not define "substantiation." For this guidance, we drew upon our own expertise with respect to the regulations and case law regarding substantiation of various statements that may be made in the labeling of dietary supplements, conventional foods, and drug products (recognizing that conventional foods and drugs are regulated differently from dietary supplements),...[emphasis added] <a href="http://wm.cfsan.fda.gov/~dms/dsclmgui.html">http://wm.cfsan.fda.gov/~dms/dsclmgui.html</a>

<sup>&</sup>lt;sup>2</sup> The three memoranda supporting the motions to exclude the five witnesses are essentially identical. They each contain an introduction and a Legal Standard for Admissibility of Expert Testimony which make identical arguments. All three memoranda then argue that each proffered expert should be excluded because they are not qualified and their testimony is irrelevant and unreliable. Respondents' opposition addresses all three motions and supporting memoranda.

- the witnesses lack "the knowledge, skill, experience, training or education required to testify as an expert on Respondents' claims…";<sup>3</sup>
- 2. the witnesses' opinions "are irrelevant to the issues of the case;" and
- the witnesses' opinions "are unreliable as they are not grounded in sufficient facts and data."

In order to make these arguments Complaint Counsel must stand *Daubert* on its head. In fact, the wholesale manner in which Complaint Counsel urges this court to treat Respondents' proffered expert witnesses resembles the *Frye* standard that limited scientific evidence to that which is "generally accepted" in its field. This was the standard that *Daubert* overturned. For the reasons set out below the court should reject Complaint Counsel's motions.

#### II. COMPLAINT COUNSEL MISSTATES THE STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY ESTABLISHED BY DAUBERT

*Daubert* overturned the *Frye* test, which limited expert testimony to scientific evidence that is generally accepted in its field. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993); *Frye v. U.S.*, 293 F. 1013 (D.C.Cir. 1923). The court overturned *Frye*, relying on the Federal Rules of Evidence and saying, "Given the Rules' permissive backdrop and their inclusion of a specific rule on expert testimony that does

<sup>&</sup>lt;sup>3</sup> Respondents make the following statements about the four contested products: 1) About Bioshark: "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 . . . 2) About 7 Herb Formula: "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria" 3) About 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. 4) About 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."

not mention 'general acceptance,' the assertion that the Rules somehow assimilated *Frye* is unconvincing. *Frye* made 'general acceptance' the exclusive test for admitting expert scientific testimony. That austere standard, absent from and incompatible with the Fed.R.Evid., should not be applied in federal trials." *Daubert* at 2794. Complaint Counsel seeks to return to the austere standard overturned by the court in *Daubert*.

The Daubert Court announced that, under the new standard, when "Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to R.104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue."<sup>4</sup>

Each of Respondents' proffered expert witnesses has scientific knowledge that Respondents argue will assist the trier of fact. Specifically, the knowledge that these experts have about herbal dietary supplements and the accepted scientific methods used to evaluate them offers aid to the court in understanding the facts of the case. Drs. Duke and Lamont were specifically asked to evaluate the claims made for the DCO products and the information available to support them including Dr. Lamont's review of all DCO information provided as evidence in this proceeding.

Dr. Duke concluded:

<sup>&</sup>lt;sup>4</sup> Footnote 10 of the *Daubert* opinion reads: Rule 104. Preliminary Questions: (a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges. (b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition. These matters should be established by a preponderance of proof. See *Bourjaily* v. *United States*, <u>483 U.S. 171</u>, 175-176 (1987).

1. There is a reasonable basis for the claims that the ingredients of 7 Herb Formula "..., fights tumor formation, and fights pathogenic bacteria." Report of Expert Witness James Duke, p. 13.

2. 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. . ." *Id.* 

3. 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." *Id*.

Dr. LaMont concluded:

1. "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. GDO also contains turmeric, feverfew and quercitin, 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. Report of Expert Witness Sally LaMont, p. 40 [Exhibit A to Complaint Counsel's Motion to Exclude Testimony and Report of Sally LaMont]

2. There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria. *Id.* 

3. There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing...[and that] these ingredients assist the body in fighting cancer, cachexia and... the destructive effects of radiation and chemotherapy treatments. *Id.* 

4. 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 [sic] has been demonstrated to inhibit tumor growth in some studies." *Id.* 

Dr. Lehr and Mr. Dews offered opinions and gave testimony on their familiarity

with various DCO products and in Dr. Lehr's case with Respondents. Mr. Dews, who

has nearly 40 years as an herbal product manufacturer, described how he created the

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formula for 7 Herb Formula and described the standard of knowledge about each of its ingredients as contained in monographs, the herbal Physicians Desk Reference as it is known among herbalists.

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Dr. Lehr, who, at the age of 74 has spent nearly 50 years designing and overseeing scientific studies and examining and evaluating scientific questions, found certain DCO products to be personally useful and undertook, long before this case began, to evaluate the scientific foundations of the DCO activities. He concluded that "DCO brings a highly credible scientific rigor to their products." Report of Expert Witness Jay Lehr, p. 4.

Dr. Roy reviewed the pitfalls of relying on single entity chemical testing for evaluating drugs as a way to evaluate herbs.

Complaint Counsel ignores all this information, including the role that DSHEA<sup>5</sup> plays in this case and asks the court to ignore it as well. Complaint Counsel jumps to the self-serving conclusion (without any evidence) that DCO's supplement claims are the same as explicit cancer cure claims.

Most specifically, Complaint Counsel ignores the purposes for which the expert testimony is offered. They argue that expert testimony should be offered only in the context of their view that this case is about drugs, express cancer cure claims and

<sup>&</sup>lt;sup>5</sup> FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading. FDA's postmarketing responsibilities include monitoring safety, e.g., dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature.

classical pharmaceutical testing. To the contrary, Respondents deny that the products that DCO makes available as part of its mission are drugs—in fact its mission is to create adjuncts and alternatives to drugs. Respondents deny that they claim to cure cancer--in fact they believe that the body has innate healing capabilities that the products that they make available assist. It is to cast light on these and related facts in the case that Respondents proffer their five expert witnesses.

Dr. Duke, who is thoroughly familiar with all the herbal ingredients in DCO products, is offered to "Review and offer opinion supported by evidence and experience on the ingredients of the challenged products; to review the science of herbal efficacy; and to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals." Report of Expert Witness James Duke, p. 1. Complaint Counsel argue that only knowledge about scientific testing of drugs for cancer cure capabilities is relevant to this case and that the nearly fifty years that Dr. Duke has spent working on a daily basis with the science of herbs, including nearly 30 years for the U.S. government, is irrelevant to the issues in this case which is about herbal supplements.

Dr. LaMont is offered: "As an expert in naturopathic medicine, 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." LaMont Deposition Transcript, dated February 17, 2009, pp. 7:20 – 8:2. Complaint Counsel moves to eliminate Dr. LaMont's testimony because she is an herbal expert and not a cancer cure expert--a basis for which she is not offered.<sup>6</sup>

<sup>&</sup>lt;sup>6</sup>In their motion for summary decision, Respondents further identified the credentials of Drs. Duke and LeMont, saying "By way of example, DCO expert witness Dr. Sally LaMont is a licensed naturopath and

To reiterate in the clearest of terms, Drs. Duke and LaMont offer testimony that illuminates and corroborates DCO's dietary supplement claims, which are at the heart of this case. Mr. Dews, the formulator of the 7 Herb Formula provides the same information about that DCO product. Respondents argue that the purported, and denied, explicit cancer claims, attributed to Respondents by Complaint Counsel are peripheral to this case.

Drs. Roy and Lehr offer opinions and testimony about the structure of science and the role it plays in addressing various facts about health, herbs and claims. This information is crucial to understanding the nature of the conflict between the parties.

Complaint Counsel's quarrel goes to the weight to be given to the testimony of

the proffered experts, not the admissibility of their testimony altogether. As stated by the

#### Daubert Court:

Vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. See *Rock v. Arkansas*, 483 U.S. 44, 61 (1987). Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, Fed. Rule Civ. Proc. 50 (a), and likewise to grant summary judgment, Fed. Rule Civ. Proc. 56. [citations omitted.] These conventional devices, rather than wholesale exclusion . . . are the appropriate safeguards where the basis

acupuncture practitioner. Her expertise includes the use of natural dietary supplements for healing and wellness. Dr. LaMont, who has testified before the California State Legislature in support of naturopathic licensing and efficacy, has issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence." Respondents' Motion for Summary Decision, p. 21.

<sup>&</sup>quot;DCO expert witness Dr. Jim Duke is a world renowned ethnobotanist who has written and lectured extensively on the medicinal qualities of plants and herbs. Dr. Duke co-authored the book *Herbs of the Bible: 2000 Years of Plant Medicine*.<sup>6[2]</sup> Dr. Duke worked for 30 years at the USDA, where he established the USDA's ethnobotanical and phytochemical data base. Like Dr. LaMont, Dr. Duke is qualified about the qualities and effects on structure and function of natural products like those used in DCO products. Dr. Duke has also issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence." *Id.* at 22.

of scientific testimony meets the standards of Rule 702. Section III, 1<sup>st</sup> para.

The proffered experts' testimony is not offered to prove the safety and efficacy of DCO's products, but rather to prove the existence of substantiation for the DCO claims about the constituent ingredients within the DCO products. Complaint Counsel's motion reveals a fundamental confusion about this point. DCO has no burden here to prove the safety and effectiveness of the Challenged Products. It is the government's burden to prove lack of safety.

Similarly, DCO is not required to produce the results of clinical trials. It is

important to note that DCO claims do not refer to a specific level of scientific support.

Furthermore, as the FTC's own guidelines state:

- The FTC's guideline for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science.<sup>7</sup>
- The benefits of a truthful claim and the cost of developing substantiation are weighed together to ensure that valuable product information is not withheld from consumers.<sup>8</sup> (Complaint Counsel's expert witness testified that it would cost a minimum of \$100 million dollars to test one component of one of DCO products.)
- In making the determination about the amount of substantiation necessary, the FTC "consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines."<sup>9</sup> [Emphasis added.]
- When a clinical trial is not possible, (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), epidemiologic evidence may be an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.<sup>10</sup>

<sup>&</sup>lt;sup>7</sup> FTC Dietary Supplement Guidelines to Industry, p 8, FTC-DCO 1050.

<sup>&</sup>lt;sup>8</sup> *Id.*, at FTC-DCO 1051.

<sup>&</sup>lt;sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> *Id.* at FTC-DCO 1052.

#### III. THE COURT SHOULD ACCEPT THE EXPERT TESTIMONY AND REPORTS OF THE FIVE WITNESSES PROFFERED BY RESPONDENTS AS EXPERTS

#### A. The Five Witnesses Proffered as Experts by Respondents Are Qualified to Testify as Experts in This Case

Complaint Counsel's objection to the proffered experts' qualifications, again, either misrepresents, or at least confuses, the issues. Complaint Counsel dismisses the expertise of Respondents' proffered experts because they are not qualified to testify "about claims . . . that the DCO products prevent, treat or cure cancer or tumors." DCO does not offer its experts for that purpose.

Respondents' expert witness testimony, like the conclusions in the written expert reports, is consistent not only with DCO's dietary supplement claims and the substantiating literature, that testimony is also wholly consistent with the theme throughout the entire DCO mosaic that the Challenged Products build the immune system and can assist with conventional cancer treatment.

By way of one specific example, DCO represents that GDU is an "adjunct" to cancer therapy, not a replacement for it. By definition, as an *adjunct* to cancer therapy, DCO is representing that its product is an auxiliary substance.

DCO also asks the Court to recall that the DCO website contains appropriate disclaimers, as cited in the DCO Motion for Summary Decision.

Complaint Counsel argues that Respondents' proffered experts lack "the knowledge, skill, experience, training or education required to testify as an expert on Respondents claims..." However, the facts are that that all the five proffered experts are qualified by knowledge, skill, experience, training and education to offer opinions on the

matters for which they are proffered—namely herbal supplements, herbal supplement standards, herbal product claims and herbal supplements science as well as appropriate science for evaluating herbs.

Drs. Duke and LaMont and Mr. Dews have extensive knowledge, training, experience, skill, and education in the field of herbal supplements, herbal supplement effects and the scientific knowledge underpinning herbal usage. Drs. Roy and Lehr are similarly qualified to offer opinions on the nature of science and what it is appropriate to rely on in evaluating substances such as herbs. Experience alone would be enough to qualify these individual as experts.<sup>11</sup> However, they have a great deal more than their experience to qualify them.

Complaint Counsel argues that to be an expert a witness must be steeped in the specific details of the products of the organization against whom the complaint has been brought. However, the Note to Rule 702 says otherwise. It says:

If the expert purports to apply principles and methods to the facts of the case, it is important that this application be conducted reliably. Yet it might also be important in some cases for an expert to educate the fact finder about general principles, without ever attempting to apply these principles to the specific facts of the case. For example, experts might instruct the fact finder on the principles of thermodynamics, or blood clotting, or on how financial markets respond to corporate reports, without ever knowing about or trying to tie their testimony into the facts of the case.<sup>12</sup>

<sup>&</sup>lt;sup>11</sup>Nothing in this amendment is intended to suggest that experience alone - or experience in conjunction with other knowledge, skill, training or education - may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience NOTES TO RULE 702 HISTORY: (Jan. 2, 1975, P.L. 93-595, § 1, 88 Stat. 1937.)Notes of Advisory Committee on Rules. http://www.law.cornell.edu/rules/fre/ACRule702.htm

<sup>&</sup>lt;sup>12</sup> NOTES TO RULE 702 HISTORY: (Jan. 2, 1975, P.L. 93-595, § 1, 88 Stat. 1937.) Notes of Advisory Committee on Rules. http://www.law.cornell.edu/rules/fre/ACRule702.htm

#### **B.** Respondents' Experts Offer Testimony and Reports Which Contain Expert Opinion That is Relevant to the Issues in This Case

Complaint Counsel next objects to the five witnesses on the basis that their testimony is not relevant. Again, Complaint Counsel makes two errors. First, Complaint Counsel ignores the difference between the weight of expert testimony and the admissibility of expert testimony. Second, Complaint Counsel forces into this case an issue and a burden that does not belong in it, i.e., it is not DCO's burden to prove the safety and efficacy of its products in this forum. Rather, DCO must show – after the FTC has met its burden – that it relied on appropriate substantiation for the claims that it made. Drs. Duke's and LaMont's and Mr. Dews' experience with herbal supplements also allows them to testify about the policy issues attendant on the cost and quantity of substantiation for dietary supplements and their constituent ingredients. In this regard, Drs. Duke and LaMont's testimony not only addresses the elements of proof required by 15 USC §45(n), their testimony is the only evidence offered to date on those elements. As a result, their opinions are certainly relevant.

Similarly, Drs. Roy and Lehr offer a combined hundred years of science in participating in, conducting and overseeing the construction of scientific studies in accordance with the principles of science—creating and challenging a hypothesis-- set out in *Daubert*. Their considered opinions on the nature of science in relation to the products challenged by Complaint Counsel and the relationship between that science, those products and the claims made by Respondents are crucial and highly relevant matters for this case.

#### C. The Five Witnesses Proffered by Respondents as Experts Offer Testimony and Reports Which Contain Expert Opinions Relevant to the Issues in this Case Which are Reliable

Finally, Complaint Counsel objects to the reliability of Respondents' experts' testimony. More specifically, Complaint Counsel takes issue with the experts' purported inability to testify about the safety and efficacy of the DCO products. But safety and efficacy are not the issue in this case, notwithstanding Complaint Counsel's efforts to make them so. Respondents' experts are not offered as experts on the safety and efficacy of DCO products. That's the government's burden to address under DSHEA in another forum. Respondents' experts are offered to provide information and give opinions on the quality and quantity of substantiation that exists for DCO's express claims and the nature of the science that supports those claims. That is all that is required of the experts in this case, and that is exactly what they have done and would do at trial.

#### **IV. CONCLUSION**

Respondents respectfully urge this court to deny Complaint Counsel's motion to exclude Respondents' proffered exert witnesses

Respondents have made only truthful statements, legally permitted to be made for dietary supplements and properly substantiated, and their expert witnesses are competent and reliable to opine on these matters. The five witnesses that Respondents have proffered have an extensive understanding of science, herbal supplements and the claims that the relationship between the herbs and the science permit.

A significant aspect of this case is the clash between philosophies about what consumers are allowed to hear what is the best way to help people, and how Respondents have conformed their actions to these standards. The experts proffered by Respondents have a great deal of scientific knowledge individually and collectively. Their individual and combined knowledge would be of significant value to the Court as it makes its decisions about the issues in this case.

Respondents respectfully request the Court to deny Complaint Counsel's motions and permit Respondents' experts to testify.

Respectfully submitted,

Dated: March 26, 2009.

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

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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** 

#### [PROPOSED] ORDER DENYING MOTION IN LIMINE

Upon Consideration of Complaint Counsel's Motions and Memoranda in Support of Their Motions to Exclude the Testimony and Reports of Respondents' Expert Witnesses Drs. James Duke, Sally Lamont, Rustum Roy, and Jay Lehr and Mr. James Dews, and Respondents' Opposition thereto,

IT IS HEREBY ORDERED that Complaint Counsel's Motion is DENIED.

ORDERED:

D. Michael Chappell Administrative Law Judge

Date:

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
<b>OFFICE OF ADMINISTRATIVE LAW JUDGES</b>

In the Matter of

DANIEL CHAPTER ONE, a corporation, and **Docket No.: 9329** 

# **PUBLIC DOCUMENT**

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

**CERTIFICATE OF SERVICE** 

13	
14	I certify that on March 26, 2009, I served or caused to be served the following documents
15	on the individuals listed below by electronic mail, followed by Federal Express delivery (except
16	as noted below):
17	AND REPORTS OF RESPONDENTS' EXPERT WITNESSES DRS. JAMES DUKE, SALLY LAMONT,
18	RUSTUM ROY, AND JAY LEHR AND MR. JAMES DEWS
19	RESPONDENTS' OPPOSITION TO COMPLAINT COUNSEL'S MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO DANIEL CHAPTER ONE'S FOR-PROFIT STATUS
20 21	RESPONDENTS' OPPOSITION TO COMPLAINT COUNSEL'S MOTION IN LIMINE TO PRECLUDE RESPONDENTS FROM INTRODUCING AT TRIAL EVIDENCE OF RESPONDENTS' "GOOD FAITH" AND NON-EXPERT OPINIONS ABOUT THE DCO PRODUCTS AS A DEFENSE TO LIABILITY RESPONDENTS' OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO PRECLUDE RESPONDENTS FROM INTRODUCING AT TRIAL EVIDENCE OF PURPORTED CONSUMER
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25	Service to:
26	Donald S. Clark
27	Office of the Secretary Federal Trade Commission 600 Pennsylvania Avenue, NW, Room H-135 Washington, DC 20580
28	
	Certificate of Service - 1

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1	Email: secretary@ftc.gov
2	(Original and one copy)
3	Leonard L. Gordon, Esq. (lgordon@ftc.gov) Theodore Zang, Jr., Esq. (tzang@ftc.gov)
4	Carole A. Paynter, Esq. (cpaynter@ftc.gov)
5	David W. Dulabon, Esq. (ddulabon@ftc.gov) Federal Trade Commission – Northeast Region
6	One Bowling Green, Suite 318
7	New York, NY 10004 (One paper copy each and by email)
8	Elizabeth Nach, Esq. (enach@ftc.gov)
9	Federal Trade Commission
10	Division of Advertising Practices 601 New Jersey Ave., NW
11	Washington, DC 20580 (By email only)
12	
13	Courtesy Copies (2):
14	Hon. D. Michael Chappell
15	Administrative Law Judge 600 Pennsylvania Avenue, NW, Room H-106
16	Washington, DC 20580
17	Email: oalj@ftc.gov
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19	Martin R.
20	Swankin & 1400 16 <sup>th</sup>
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