

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

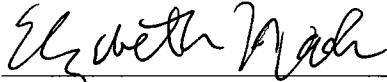
RESPONDENT'S STIPULATED MOTION FOR LEAVE TO AMEND
THEIR REPLY TO COMPLAINT COUNSEL'S PROPOSED
FINDINGS OF FACT

Complaint Counsel filed their Post Trial Brief, including Proposed Findings of Fact, in the above-captioned matter on May 28, 2009. Respondents filed their Reply Brief, including responses to Complaint Counsel's Proposed Findings of Fact, on June 11, 2009. After filing their Reply Brief, Respondents' counsel noted inadvertent errors in their responses to Complaint Counsel's Proposed Findings of Fact. Respondents' counsel conferred with Complaint Counsel regarding a proposed errata sheet correcting the errors. Complaint Counsel do not oppose the proposed amendment. Therefore, Respondents move for an order of the Court providing that:

1. Respondents' responses to Complaint Counsel's Proposed Findings of Fact numbered 51, 68, 74, 111, 135, 223, 280, 359 and 360 be, and are hereby amended by substituting the attached corrected pages: 20, 26, 28, 37, 48, 90, 106, and 123.

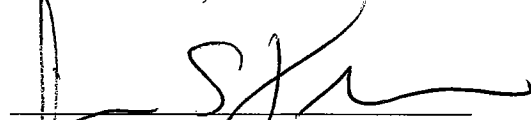
Respectfully submitted,

Dated: June 23, 2009



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Dated: June 23, 2009



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[PROPOSED] ORDER ON STIPULATION

The above stipulation is approved.

It is ORDERED that Respondents' responses to Complaint Counsel's Proposed Findings of Fact numbers 51, 68, 74, 111, 135, 223, 280, 359 and 360 be, and are hereby amended by substituting the attached corrected pages: 20, 26, 28, 37, 48, 90, 106, and 123 to Respondents' Responses to Complaint Counsel's Proposed Findings of Fact filed on June 11, 2009.

D. Michael Chappell
Administrative Law Judge

Date: _____, 2009

**IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
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In the Matter of)
DANIEL CHAPTER ONE,)
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JAMES FEIJO,)
Individually, and as an officer of)
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**ERRATA TO RESPONDENTS' RESPONSES TO
COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT**

Inadvertent errors were made in Respondents' Responses to Complaint Counsel's Proposed Findings of Fact. Specifically, there are errors in Responses to Nos. 51, 68, 74, 111, 135, 223, 280, 359, and 360. These erroneous responses are set forth below, and the corrected pages of Respondents' Responses to Complaint Counsel's Proposed Findings of Fact are attached to this submission.

RESPONSE TO FINDING NO.	RESPONSE IN ERROR	CORRECTED RESPONSE (Corrected Portions Shown in Bold Type)
51	Respondents have no specific response.	DCO's shipping and handling charge is not \$20.95 for all shipments. The shipping and handling charge varies depending on the weight and destination of the shipment (R 15 (Feijo, J., Dep. at 152-53)).

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).	The chiropractic centers that carry DCO products are owned by members or supporters of the DCO ministry. Respondents have discontinued their relationships with certain doctors because Respondents felt that those doctors were acting inconsistently with DCO's religious principles (HOJ, Feijo, J., Tr. 130).
74	There have been different versions of 7 Herb Formula (Feijo, P., Tr. 437-39).	Respondents concur.
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).	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, Bertrand , Tr. 299-300; HOJ, Harrison, Tr. 247).
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	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); BioMixx is effective in the

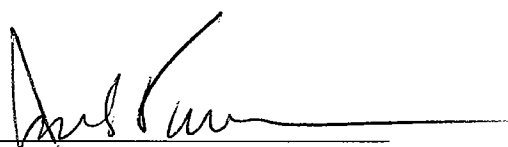
<p>treatment of cancer (Feijo, P., Tr. 354).</p> <p>With regard to "BioMixx heals the destructive effects of radiation and chemotherapy," Respondents submit that this, like all claims that Respondents actually make, is a structure or function claim permitted in support of dietary supplements.</p> <p>Respondents did make the following permissible structure/function claims:</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><i>7 Herb Formula "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"</i></p> <p><i>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-</i></p>	<p>treatment of cancer (Feijo, P., Tr. 354); and BioMixx heals the destructive effects of radiation and chemotherapy (Feijo, P., Tr. 354).</p> <p>Respondents did not make the claim, "BioMixx heals the destructive effects of radiation and chemotherapy." Rather, Respondents stated that BioMixx "is used to assist the body in fighting cancer and healing the destructive effects of radiation and chemotherapy treatments." (Feijo, P., Tr. 354-55).</p> <p>Respondents did make the following permissible structure/function claims:</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><i>7 Herb Formula "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"</i></p> <p><i>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-</i></p>
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	<p><i>inflammatory and antispasmodic activity. . ."</i></p> <p><i>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."</i></p>	<p><i>inflammatory and antispasmodic activity. . ."</i></p> <p><i>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."</i></p>
223	<p>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).</p> <p>Respondents do not claim that BioShark treats cancer (Complaint, Exh. 1; Feijo, P., Tr. 340-41). Instead, Respondents actually say, "<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>" (Feijo, P., Tr. 341).</p> <p>Respondents have adequate substantiation for their claims regarding BioShark (see Response to Finding No. 200 and Dr. LaMont's testimony and expert witness report).</p>	<p>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).</p> <p>Respondents do not claim that BioShark treats cancer (Complaint, Ex. A; Feijo, P., Tr. 340-41). Instead, Respondents actually say, "<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>" (Feijo, P., Tr. 341).</p> <p>Respondents have adequate substantiation for their claims regarding BioShark (see Response to Finding No. 200 and Dr. LaMont's testimony and expert witness report).</p>
280	<p>Respondents have no specific response.</p> <p>Respondents do not assert that the testimonials by users of DCO's products constitute substantiation, nor do Respondents claim that</p>	<p>Respondents have no specific response but note that</p> <p>Respondents do not assert that the testimonials by users of DCO's products constitute substantiation, nor do Respondents claim that</p>

	DCO's products cure, treat, or prevent cancer.	DCO's products cure, treat, or prevent cancer.
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.	See Response to Finding No. 351 above, and Respondents note that they do not claim that their products are intended to treat, cure, or prevent any disease.
360	See Response to Finding No. 353 above for the full text and context of Dr. LaMont's answer.	Respondents have no specific response.

Dated: June 17, 2009

Respectfully Submitted,



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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

DCO's shipping and handling charge is not \$20.95 for all shipments. The shipping and handling charge varies depending on the weight and destination of the shipment (R 15 (Feijo, J., Dep. at 152-53)).

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

supporters of the DCO ministry. Respondents have discontinued their relationships with certain doctors 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 dc1store.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)).

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

Respondents concur.

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

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, Bertrand, 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

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);
BioMixx is effective in the treatment of cancer (Feijo, P., Tr. 354); and
BioMixx heals the destructive effects of radiation and chemotherapy
(Feijo, P., Tr. 354).

Respondents did not make the claim, "BioMixx heals the destructive effects of radiation and chemotherapy." Rather, Respondents stated that BioMixx "is used to assist the body in fighting cancer and healing the destructive effects of radiation and chemotherapy treatments." (Feijo, P., Tr. 354-55). 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

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, Ex. A; 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

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 but note that 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

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 do not 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

Respondents have no specific response.

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.

CERTIFICATE OF SERVICE

I certify that on June 23, 2009, I filed, served or caused to be served or filed, the following documents on the individuals listed below as noted:

Respondents' Stipulated Motion for Leave to Amend their Reply Brief to Complaint Counsel's Proposed Findings of Fact

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 24, 2009) and one electronic copy to each to:


Leonard L. Gordon, Esq. (lgordon@ftc.gov)
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Federal Trade Commission – Northeast Region
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New York, NY 10004

One electronic copy to:

Elizabeth Nach, Esq. (enach@ftc.gov)

Four paper copies via hand delivery and one electronic copy to:

Hon. D. Michael Chappell
Administrative Law Judge
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Washington, DC 20580
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