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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ENFORMA NATURAL PRODUCTS, INC., ANDREW GREY, and FRED ZINOS,

Defendants.

CV 00-04376-JSL (CWx)

MEMORANDUM IN SUPPORT OF PLAINTIFF'S APPLICATION FOR AN ORDER TO SHOW CAUSE WHY DEFENDANTS ENFORMA NATURAL PRODUCTS, INC. AND ANDREW GREY AND NONPARTY MICHAEL EHRMAN SHOULD NOT BE HELD IN CIVIL CONTEMPT

DATE: Feb. 4, 2002
TIME: 1:00 pm
CTRM: 4
JUDGE: Hon. J. Spencer Letts

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I. INTRODUCTION

Plaintiff Federal Trade Commission ("Commission") respectfully seeks an Order to Show Cause why defendants Enforma Natural Products, Inc. ("Enforma") and Andrew Grey ("Grey") and non-defendant Enforma Vice President Michael Ehrman ("Ehrman") should not be held in civil contempt for violating the Stipulated Final Order and Settlement of Claims for Monetary Relief as to Defendants Enforma Natural Products, Inc. and Andrew Grey (the "Order"), entered by the Court on May 11, 2000 (attached as Exhibit 1to the Declaration of David P. Frankel) in connection with their systematic and ongoing violations of the Order. Among other things, the Order prohibits defendants and their officers, agents, and employees from making certain unsubstantiated claims in connection with the labeling, advertising, promotion, offer for sale, sale, or distribution of their products. Defendants and Ehrman have blatantly disregarded the Order by continuing to make numerous unsubstantiated claims in connection with the sale of the Enforma System, Fat Trapper Plus, and Exercise In A Bottle – products specifically covered by the Order. These continuing unsubstantiated claims go to the very heart of the Commission's Complaint and the Order entered by this Court.

Accordingly, defendants and Ehrman should be deemed to be in civil contempt and as relief for their flagrant violations be required immediately to: (1) comply with this Court's Order; (2) cease using the trade names "Fat Trapper," "Fat Trapper Plus" and "Exercise In A Bottle," because those trade names constitute unsubstantiated claims; (3) account for and turn over to the Commission for possible consumer redress or as a payment to the U.S. Treasury all gross revenues, including shipping and handling revenues, they have received from the sale of these products and the Enforma System worldwide after May 11, 2000; (4) recall from any wholesalers, distributors, fulfillment houses, catalog companies, Internet sellers and retailers any and all such products or otherwise ensure that all

packaging, labeling, advertisements and promotions containing any unsubstantiated claims encompassed by the Order are not distributed, offered for sale or sold; (5) provide to the Commission full and complete answers to all outstanding discovery requests, including deposition testimony, to all questions concerning the advertising, promotion, offering for sale and sale of and revenues derived from the Enforma System, Fat Trapper, Fat Trapper Plus and Exercise In A Bottle outside of the United States after May 11, 2000; and (6) compensate the Commission for its expenses in bringing and pursuing this application. A proposed order to show cause is lodged with this application.

II. STATEMENT OF FACTS

A. PROCEDURAL HISTORY AND PERMANENT INJUNCTION

Enforma broadcast two infomercials for its weight loss products Fat Trapper and Exercise In A Bottle, collectively referred to as the "Enforma System," approximately 48,000 times from December 1998 to May 2000. The slickly-produced infomercials featured former professional baseball player Steve Garvey and an actress falsely described as a "nutritionist," Lark Kendall (a/k/a Kendall Carson), extolling the miracle of the Enforma System and performing demonstrations purporting to show how Fat Trapper actually trapped fat and prevented its absorption by the human body. The infomercials stated, among many other claims, that "Fat Trapper blocks fat from foods that we eat, it grabs hold of the fat, it wraps it up, ties it in a bundle which is then too large to pass through the gut wall." The infomercials also claimed that Exercise In A Bottle works to burn calories "even while resting" and that consumers would "never, ever, ever, ever have to diet again."

The Commission initiated an investigation into whether these incredible claims could be substantiated. Enforma and its President, Andrew Grey, agreed to the Order, which was filed with the Complaint, requiring the payment of $10 million

in consumer redress. The Order prohibits Enforma and Grey from making unsubstantiated claims in the future and requires them to disclose in advertising that dieting and/or exercise are required to lose weight.

Paragraph I of the Order prohibits defendants (and those in active concert or participation with defendants) from representing, without competent and reliable scientific substantiation, that the Enforma System (or its components): (1) enables consumers to lose weight, avoid weight gain or maintain weight loss without the need for a restricted calorie diet or exercise; (2) prevents the absorption of fat in the human body; (3) increases metabolism at the cellular level, burns sugar or carbohydrates before they turn to fat, or burns off fat already in the human body; or (4) enables consumers to lose weight even if consumers eat foods high in fat, including fried chicken, pizza, cheeseburgers, butter, and sour cream. This provision of the Order specifically prohibits such claims that may be made "through the use of the names 'Fat Trapper,' 'Fat Trapper Plus,' and 'Exercise In A Bottle'":

I.

IT IS HEREBY ORDERED that defendants, directly or through any corporation, partnership, subsidiary, division, or other device, and their officers, agents, servants, employees and attorneys, and all other persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of the Enforma System, Fat Trapper, Fat Trapper Plus, or Exercise In A Bottle, or any other product, service or program in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of the names "Fat Trapper," "Fat Trapper Plus," and "Exercise In A Bottle," that such product, service or program:

A. Enables consumers to lose weight, avoid weight gain or maintain weight loss without the need for a restricted calorie diet or exercise;

B. Prevents the absorption of fat in the human body;

C. Increases metabolism at the cellular level, burns sugar or carbohydrates before they turn to fat, or burns off fat already in the human body; or

D. Enables consumers to lose weight even if consumers eat foods high in fat, including fried chicken, pizza, cheeseburgers, butter, and sour cream,

unless at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph III of the Order prohibits the dissemination of express or implied representations concerning weight loss benefits, performance, or efficacy of defendants' products without competent and reliable scientific evidence substantiating these representations:

III.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, partnership, subsidiary, division, or other device, and their officers, agents, servants, employees, and attorneys, and all other persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of the Enforma System, Fat Trapper, Fat Trapper Plus, or Exercise In A Bottle; or any other food, dietary supplement, drug, device; or weight loss product, service, or program; in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the health or weight loss benefits, performance, safety, or efficacy of such product, service or program, unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Finally, Paragraph IV of the Order prohibits defendants from "misrepresenting, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study, or research":

IV.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, partnership, subsidiary, division, or other device, and their officers, agents, servants, employees, and attorneys, and all other persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising,

> promotion, offering for sale, sale, or distribution of any product, service or program, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study, or research.[1]

The Complaint and Order were filed on April 25, 2000 and the Court entered the Order on May 11, 2000. Enforma ceased broadcast of the two infomercials in the United States, but continued to advertise Fat Trapper, Fat Trapper Plus and Exercise In A Bottle through other means.[2]

Enforma and Grey were defendants in the underlying action.[3] Grey is President and Chief Executive Officer of Enforma. He has final approval authority over Enforma's advertising and has ultimate responsibility for determining whether advertising claims are substantiated. Ehrman is Enforma's Executive Vice President of Sales and Marketing. Although Ehrman was not a defendant in the underlying action, he had actual notice of the Order and signed an acknowledgment

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[1] The Order also required defendants to pay $10 million as consumer redress over six months. These payments were made in a timely manner. The payments were intended as redress for past law violations and not as a down payment on future infractions.

[2] In August 2000, the Commission also filed a complaint against the producer of the infomercials, Modern Interactive Technology, Inc., and its principals; the celebrity endorser, Steve Garvey, and his management company; and Lark Kendall, a/k/a Kendall Carson, the purported "nutritionist" who co-hosted the infomercials with Garvey. *FTC v. Garvey, et al.*, CV 00-09358-GAF (CWx) (C.D. Cal.). Lark Kendall settled the claims against her. Modern Interactive Technology and its principals were granted summary judgment. Discovery in the *Garvey* case is complete and the pretrial conference is set for January 14, 2002.

[3] A third defendant, Fred Zinos, settled separately with the Commission and has had no further involvement with the Enforma System. The Commission is not seeking to hold Mr. Zinos in contempt.

of its receipt. Ehrman has responsibility for creating and developing advertising for the company's products and he reviews substantiation for such advertisements.

B. DEFENDANTS' AND EHRMAN'S POST-ORDER CONDUCT

After entry of the Order on May 11, 2000, Enforma, Grey and Ehrman have continued to offer for sale and sell the Enforma System, Fat Trapper Plus and Exercise In A Bottle through retail stores, the company's continuity program, and the Internet. They have also continued to make numerous representations for those products on the Internet, product packaging, television commercials and elsewhere. For example, a 3 minute, 30 second infomercial that appeared on Enforma's official website beginning May 12, 2000, one day *after* entry of the Order, stated:

- "Fat Trapper acts like a magnet, absorbing some of the fat you eat." (Exh. 2 at 4.)
- The psyllium contained in Fat Trapper Plus "increases the effectiveness of chitosan in trapping the fat" in the human body. (Exh. 2 at 5.)
- "Fat Trapper prevents some of the excess fat from being absorbed. It simply passes through your system. No fat storage. It's as if you never ate that fat at all." (Exh. 2 at 5.)
- "Here's how it works. Our complete formula contains two all-natural fibers that work together. The first is a soluble fiber, chitosan, that traps some of the fat. The second is an insoluble fiber from plants that increases the effectiveness of chitosan in trapping the fat as well as in helping your overall digestion." (Exh. 2 at 5.)
- "Remember, sugar and carbohydrates can quickly turn to fat. All natural Exercise In A Bottle contains pyruvate, an important element that helps your body use up carbohydrates and sugars as fuel for metabolism." (Exh. 2 at 6.)

- "Exercise In a Bottle helps your body use sugar and carbohydrates as fuel for metabolism." (Exh. 2 at 4.)
- "So, you trap the fat with Fat Trapper, use up the sugar and carbohydrates faster with Exercise In A Bottle and you can regain the freedom to eat your favorite foods." (Exh. 2 at 7.)
- "We know that the Enforma System works because the ingredients are backed by years of scientific studies including clinical trials." (Exh. 2 at 7.)
- "And we know the Enforma System works because millions of consumers have purchased the system and have lost 10, 20, 30, 40, 50, even 100 pounds." (Exh. 2 at 8.)

At the time this infomercial was available for viewing on Enforma's web site, the packaging of each bottle of Fat Trapper Plus and Exercise In A Bottle and commercials running on television also made similar sweeping claims about the products:

- Fat Trapper Plus "[r]educes calorie intake from fat." (Exh. 3.)
- "We all know how hard it is to change eating habits when it comes to eating fatty food, the habit is just about impossible to break. That's why we invented all natural FAT TRAPPER PLUS™, designed to reduce the amount of fat our bodies can absorb from the foods we love." (Exh. 3.)
- "Do you dream about eating wonderful fat filled foods? Stop dreaming and take FAT TRAPPER PLUS™. All natural FAT TRAPPER PLUS™ binds and entraps fat, reducing the amount of fat the body absorbs. This results in an effective way to reduce calories from fat." (Exh. 4.)
- "Clinical studies indicate that FAT TRAPPER PLUS™ absorbs some of the fat from high fat foods." (Exh. 4.)
- Fat Trapper Plus is "**CLINICALLY PROVEN TO ABSORB FAT**" (Exh. 4.) (emphasis in original)

- "All natural FAT TRAPPER PLUS™ binds and entraps fat, reducing the amount of fat the body absorbs. This results in an effective way to reduce calories from fat." (Exh. 4.)
- "All natural FAT TRAPPER PLUS™ is a special blend of natural fibers that binds and entraps some of the fat you eat, reducing the amount of fat the body absorbs. This results in an effective way to reduce calories from fat." (Exh. 5.)
- Fat Trapper Plus "may be more effective when used together with Enforma's companion products, EXERCISE IN A BOTTLE®, HUNGER EASE™, CARB TRAPPER PLUS™, and DESSERT AVERT®." (Exh. 4.)
- Fat Trapper Plus "may be even more effective when used together with Enforma's companion product, EXERCISE IN A BOTTLE™." (Exh. 3.)
- "**HOW IT [EXERCISE IN A BOTTLE] WORKS:** Pyruvate is an important part of the body's process that utilizes carbohydrates and fat as fuel (energy) for metabolism. Although Pyruvate is naturally present in small quantities in the body, the introduction of greater concentrations of Pyruvate has been found to stimulate the body's metabolism. This process occurs even while resting!" (Exh. 6.)

When the Commission requested scientific substantiation for many of these claims, Enforma provided several volumes of documents, most of which had already been submitted during the previous investigation into their advertising claims in the infomercials. Interestingly, as the Commission requested substantiation for newer claims, Enforma often simply revised or deleted those claims from its advertising or packaging. Thus, several – but not all – of the egregious claims above have been discontinued. Currently, however, Enforma's advertising on Fat Trapper Plus packaging and in television commercials still claims

that the product traps fat in fatty foods, implying that consumers can continue to eat high calorie and fatty foods and still lose weight:

- "TRAP THE FAT" (Exhs. 5, 7.)
- "Fat Trapper's main ingredient has been shown to trap some of the fat in the foods you love." (Exhs. 5, 7.)
- "Studies indicate that the main ingredient in Fat Trapper Plus™ traps some of the fat in the foods you love." (Exhs. 5, 7.)

In addition, of course, the trade name "Fat Trapper Plus" has all along made an express claim that the product traps fat in humans when taken at the recommended dose, and the name "Exercise In A Bottle" has represented that it provides some of the health, weight loss or weight management benefits of exercise when taken at the recommended dose.

Although defendants have submitted volumes of purported substantiation, they have not provided any *competent and reliable evidence* to support the claims made above, and therefore are in contempt of court for their actions in advertising and promoting Fat Trapper Plus and Exercise In A Bottle.

III. LEGAL ARGUMENT

Courts possess the inherent authority to enforce compliance with their orders through civil contempt. *See, e.g., Gunn v. University Committee to End War*, 399 U.S. 383, 389, 90 S. Ct. 2013, 2016-17, 26 L. Ed. 2d 684, 688-89 (1970); *Shillitani v. United States*, 384 U.S. 364, 370, 86 S. Ct. 1531, 1535-36, 16 L. Ed. 2d 622, 627 (1966). To establish liability for civil contempt, the plaintiff must show by clear and convincing evidence that the defendant has violated a specific and definite order of the court. *FTC v. Affordable Media, LLC*, 179 F.3d 1228, 1239 (9th Cir. 1999). Clear and convincing evidence requires proof by more than a preponderance of the evidence but less than proof beyond a reasonable doubt. *See, e.g., Bala v. Idaho State Bd. of Corrections*, 869 F.2d 461, 466 (9th Cir.

1989). The burden is on the complainant to demonstrate by clear and convincing evidence that the defendant is in contempt; then the burden shifts to the contemnor to demonstrate why he was unable to comply. *Affordable Media*, 179 F.3d at 1239. The contemnor must show he took every reasonable step to comply. *Stone v. City & County of San Francisco*, 968 F.2d 850, 856 n.9 (9th Cir. 1992).

The elements that must be proven to establish civil contempt are: (1) the existence of a court order; (2) the order either prohibited or required certain conduct by the alleged contemnor; and (3) the alleged contemnor failed to comply with such order. *Petrolos Mexicanos v. Crawford Enters., Inc.*, 826 F.2d 392, 401 (5th Cir. 1987). The failure to comply need not be willful, and may in fact consist of a party's failure to take all reasonable steps within the party's power to comply. *In re Dual-Deck Video Cassette Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir. 1993). The Ninth Circuit has also stated: "Intent is irrelevant to a finding of civil contempt and, therefore, good faith is not a defense." *Stone*, 968 F.2d at 856.

A. CLEAR AND CONVINCING EVIDENCE PROVES EACH OF THE ELEMENTS ESTABLISHING DEFENDANTS' AND EHRMAN'S CIVIL CONTEMPT

1. Defendants And Ehrman Are Bound By A Valid, Effective Order

The Order entered by this Court on May 11, 2000 is a valid court order that requires defendants and Ehrman to have competent and reliable scientific substantiation for certain types of claims and prohibits them from misrepresenting the results of scientific tests or studies in their advertisements. Federal court injunctions bind not only the parties but also "those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise." Fed. R. Civ. P. 65(d). On June 1, 2000, Ehrman acknowledged that he was a person having responsibilities with respect to the subject matter of the Order and that he received a copy of the Order within the prescribed time frame.

See Exh. 8.[4] As Enforma's Executive Vice President of Sales and Marketing, Ehrman is an agent or employee of defendant Enforma and in active concert or participation with defendants Enforma and Grey with actual notice of the Order and its terms. Thus, he is also bound by the Order.

2. The Order Requires Certain Substantiation And Prohibits Certain Misrepresentations By Defendants And Ehrman

Paragraph I of the Order specifically enjoins defendants and Ehrman from disseminating certain specified express or implied claims unless they possess "competent and reliable scientific evidence that substantiates the representation[s]." Order ¶ I.[5] Paragraph III of the Order enjoins defendants and Ehrman from disseminating express or implied representations concerning weight loss benefits, performance or efficacy of their products, unless they possess "competent and reliable scientific evidence that substantiates the representation[s]." *Id*. ¶ III. Paragraph IV of the Order prohibits defendants and Ehrman from "misrepresenting, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study, or research." *Id.* ¶ IV.

3. Defendants And Ehrman Failed To Comply With The Order

Defendants and Ehrman have blatantly ignored the core conduct provisions of the Order by continuing to disseminate the Enforma System, Fat Trapper Plus

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[4] Ehrman's "acknowledgment" form was required by Paragraph IX of the Order.

[5] "Competent and reliable scientific evidence" is defined in the Order to mean "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Exh. 1 at 3. Thus studies and reports offered by Enforma as support are not necessarily adequate "substantiation;" they must fit the above criteria of reliability.

and Exercise In A Bottle (products specifically identified in the Order) both without adequate substantiation for various claims and by misrepresenting the results of studies. This flagrant, consistent and pervasive transgression of the Order has likely caused additional millions of dollars in injury to vulnerable consumers who seek the elusive miracle pill that will permit them to enjoy fatty foods without experiencing the weight gain that such foods typically cause.[6] Although the extreme claims from the original infomercials are, for the most part, no longer being disseminated, Enforma persists in using express and strongly implied claims to continue to spread the same message from the infomercials – that with Fat Trapper Plus, consumers can eat fatty foods without fear that the fat will be absorbed by the body, and that with Exercise In A Bottle, consumers can replace exercise with a pill.

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[6] In 1999, an estimated 61 percent of all U.S. adults were overweight or obese. Overweight and obesity are increasing in both genders and among all population groups. Overweight and obesity substantially raise the risk of illness from high blood pressure, high cholesterol, type 2 diabetes, heart disease and stroke, gallbladder disease, arthritis, sleep disturbances and problems breathing, and certain types of cancers. Approximately 300,000 deaths a year in this country are currently associated with overweight and obesity. Obese individuals also may suffer from social stigmatization, discrimination, and lowered self-esteem. The number of overweight children, adolescents, and adults has risen over the past four decades. Today there are nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980. In 1995, the total (direct and indirect) costs attributed to obesity amounted to an estimated $99 billion. In 2000, the total cost of obesity was estimated to be $117 billion ($61 billion direct and $56 billion indirect). *See* "Healthy People 2010," Dep't of Health and Human Services, Office of Disease Prevention and Health Promotion, http://www.health.gov/healthypeople/Document/HTML/Volume2/ 19Nutrition.htm; U.S. Dep't of Health and Human Services, "The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity," http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf (released Dec. 13, 2001).

In response to the Commission's requests in the compliance investigation, Enforma provided volumes of purported "substantiation" for their claims. The majority of this substantiation, however, is material that had already been submitted to the Commission during the investigation that led to the original federal court complaint and Order in this case. Now, however, Enforma has identified two experts, Harry G. Preuss, M.D. and Irwin Gross, M.D., who supposedly substantiate the claims made, albeit only the chitosan or Fat Trapper/Fat Trapper Plus claims.[7] Dr. Preuss, a professor at Georgetown University Medical School, has expressed the opinion that the chitosan in Fat Trapper Plus absorbs some of the fat eaten by consumers, and that chitosan, *in conjunction with diet or exercise*, can be an effective weight loss supplement. Dr. Gross is listed as the author of a study pertaining to the fat trapping effects of Fat Trapper Plus. The Commission has deposed these experts, and reviewed the substantiation and expert opinions in consultation with an outside expert, David Levitsky, Ph.D., a professor in the Division of Nutritional Sciences and the Department of Psychology at Cornell University.

Dr. Levitsky has examined in detail the materials relied upon by Enforma's experts in support of their opinion that the chitosan or Fat Trapper Plus claims are substantiated. Some of these materials describe studies that purport to show a positive effect for Fat Trapper Plus in blocking the absorption of fat. However, Dr. Levitsky rejects this evidence on a number of grounds. Some of the studies are inappropriate in that they appear to be measuring delays in digestion, which fiber can cause, rather than failure to digest fat, which is the claim. In some cases the

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[7] Notably, Enforma, Grey, and Ehrman did not designate an expert to support their claims for Exercise In A Bottle or its main active ingredient, pyruvate. Thus, they have apparently conceded their inability to provide competent and reliable scientific evidence for *any* claim about this product, including the highly dubious assertion that it speeds up the metabolism, "even while resting."

studies contain severe methodological flaws.[8] In others, the statistical analysis was conducted improperly. Dr. Levitsky's declaration, submitted with this application, sets out why the submitted materials do not constitute competent and reliable scientific evidence supporting Enforma's claims.

a. Enforma has no competent and reliable scientific evidence supporting its claims that Fat Trapper Plus traps or absorbs fat or is clinically proven to do so

Enforma has repeatedly advertised since May 11, 2000 that Fat Trapper Plus "absorbs" or "traps" fat. Indeed, the very name on the bottle explicitly conveys the message that Enforma's product, when taken at the recommended dose, traps fat eaten by consumers. The substantiation provided by Enforma, however, does not support this claim. First, most of the studies relied upon do not test Enforma's product. The only study on Fat Trapper Plus itself allegedly showing a positive effect is, as stated by the Commission's expert, "poorly designed, poorly conducted," and "obtained results that were too variable to be reliable." Levitsky Decl., ¶ 27. In fact, Dr. Preuss does not even rely upon it to support his opinions. Exh. 9 at 119:2-120:9. The "author," Dr. Irwin Gross (one of defendants' retained experts), conceded that he did not design or conduct the study, nor did he even review the underlying data prior to writing his report. He simply drafted a written report (hereinafter referred to as the "Gross report") based on data calculations provided to him. Exh. 10 at 36:24-42:7. The methodology of the Gross report – measuring blood triglyceride levels instead of fecal fat excretion – was only an indirect measure of whether fat was indeed being "trapped" by Fat Trapper Plus. Levitsky Decl., ¶¶ 28. Also, the participants received varying dosages of Fat Trapper Plus or another chitosan product, Liposan Ultra; there is no information provided as to whether Liposan Ultra is identical to Fat Trapper Plus or whether

[8] In some studies, for example, the authors selected only some of the results for inclusion in the analysis.

these varying dosages can be extrapolated to the recommended dosage of Fat Trapper Plus. To the contrary, Dr. Levitsky opines that results from substantially higher dosages cannot be extrapolated to Fat Trapper Plus' recommended dosage. *Id*. ¶ 31. Furthermore, some of the subjects were tested more frequently than others, and only the positive results were included in the data calculations, other examples of the improper analysis employed. *Id*. ¶ 33.

Second, the other chitosan studies relied upon by Dr. Preuss for Enforma's claim that Fat Trapper Plus indeed traps fat are similarly unreliable. They used other chitosan-based products that did not necessarily have the same composition as Fat Trapper Plus. The only three studies done on humans, when analyzed properly, found no statistically significant evidence of fat absorption by chitosan. *Id*. ¶¶ 35-47. In addition, several other fecal fat extraction studies have not found any statistically significant increase in fat absorption with chitosan. *Id*. ¶¶ 50-55. Thus, contrary to Enforma's explicit claims and the name of the product, there is no competent and reliable scientific evidence, much less clinical evidence, that Fat Trapper Plus actually absorbs any of the fat eaten by consumers. *See id.* ¶¶ 26, 56. Defendants and Ehrman have therefore made unsubstantiated claims that Fat Trapper Plus traps fat and is clinically proven to prevent absorption of fat in the human body, in violation of Paragraphs I, III, and IV of the Order.

b. Enforma has no competent and reliable evidence that Fat Trapper Plus reduces calorie intake from fat

Enforma's current claim on the packaging that Fat Trapper Plus reduces calorie intake from fat is equally unsubstantiated. The claim assumes that Fat Trapper Plus in fact absorbs dietary fat in humans, but, as described above, Fat Trapper Plus has not been shown by competent and reliable evidence to trap fat. Therefore, defendants and Ehrman's unsubstantiated claim that Fat Trapper Plus reduces calorie intake from fat violates Paragraphs I and III of the Order.

c. Enforma has no competent and reliable evidence that the psyllium in Fat Trapper Plus increases chitosan's effectiveness in trapping fat

Although Enforma claimed in its advertising that the psyllium[9] in Fat Trapper Plus increases chitosan's effectiveness in trapping fat, there is no evidence to support this representation. Enforma provided absolutely no substantiation for this claim in response to the Commission's request. Even Dr. Preuss, in his deposition, testified that he could not say whether the psyllium in Fat Trapper Plus helps the chitosan in any way. Exh. 9 at 175:7-22. Indeed, there is no scientific research that even addresses this issue. Levitsky Decl., ¶ 57. Nor has Enforma provided any substantiation regarding the fat trapping properties, if any, of psyllium itself. Enforma's current packaging continues to claim that "[t]he combination of soluble and insoluble fibers [*i.e.*, psyllium and chitosan] traps some of the fat, reducing the amount of fat the body absorbs." As stated above, there is no competent and reliable scientific evidence to support this claim. *See id.* Therefore, by making this claim without any substantiation, defendants and Ehrman violated Paragraphs I and III of the Order.

d. Enforma has no competent and reliable evidence that the pyruvate in Exercise In A Bottle stimulates metabolism, even while resting

One of the most deceptive and potentially harmful claims in Enforma's marketing was the representation that the pill, Exercise In A Bottle, essentially takes the place of actual physical activity. The advertisements and packaging for Exercise In A Bottle stated that it increases metabolism "even while resting." In fact, there was no substantiation for this outrageous assertion. First, Enforma offered no pyruvate studies using the dosage contained in its product. The two studies in which pyruvate's effect on metabolism was measured used *16 and 30*

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[9] Enforma's ads sometimes refer to psyllium as "an insoluble fiber from plants." In fact, psyllium is actually a soluble fiber. Levitsky Decl., ¶ 57.

times the dosage found in Exercise In A Bottle, which is a mere one gram per day. Levitsky Decl., ¶¶ 58-60. Second, even at these high doses, neither of those studies found that pyruvate had a statistically significant effect on resting metabolism. *Id*. The studies offered are thus not competent and reliable scientific evidence and did not substantiate Enforma's claims. *See id.* Defendants and Ehrman therefore violated Paragraphs I and III of the Order.

e. Enforma has no competent and reliable evidence that the pyruvate in Exercise In A Bottle helps the body use sugar and carbohydrates as fuel for metabolism

Enforma also continues to imply that its product Exercise In a Bottle burns sugar and carbohydrates, presumably before they turn to fat, *e.g.*, "Supports Metabolism." But it offers no support for this claim. The only two studies that even looked at carbohydrate metabolism with pyruvate use found no difference. Levitsky Decl., ¶¶ 61-63. Moreover, both of these studies used dosages of pyruvate far in excess of that found in Exercise In A Bottle. *Id*. If high doses of pyruvate have no effect whatsoever on carbohydrate metabolism, Enforma cannot possibly claim that the minuscule doses in Exercise In A Bottle have an effect. *See id*. Because this claim is not substantiated with competent and reliable scientific evidence, defendants and Ehrman are in violation of Paragraphs I and III of the Order.

f. Enforma has no competent and reliable evidence that its products are more effective when used together

Enforma claimed in its advertising that its products Fat Trapper Plus and Exercise In A Bottle may be more effective when used together, or when used with Enforma's other dietary supplements. There are numerous problems with this claim. First, the claim implies that Fat Trapper Plus and Exercise In A Bottle are effective at all, which has not been established by competent and reliable scientific evidence. *See* Section III.A.3.a-e, *supra*. Second, in response to the Commission's request for substantiation for this claim, Enforma merely provided

documents purporting to demonstrate the properties of each product's ingredients. No evidence was provided to show that the products were "more effective" when used together. Enforma's experts also have not testified that the products are more efficacious when used together. Because these claims constituted unsubstantiated representations about the efficacy of Fat Trapper Plus and Exercise In A Bottle, defendants and Ehrman violated Paragraph III of the Order.

g. Enforma's claim that the Enforma System "works" based on the alleged experience of "millions" of people is not substantiated

Enforma's advertisements also claimed that "the Enforma System works because millions of consumers have purchased the system and have lost 10, 20, 30, 40, 50, even 100 pounds." First, it is not known whether millions of consumers have actually lost weight, and in the amounts claimed. Enforma provided the Commission with a list of approximately 1,100 purchasers, many but not all of whom, claimed to have lost some weight. Second, that consumers purchased the system and claimed to lose weight is mere anecdotal evidence, which cannot constitute competent and reliable scientific substantiation of the claims made by defendants. *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1273 (S.D. Fla. 1999) (testimony of consumer witnesses who allegedly lost substantial amounts of weight on product was "anecdotal information" that did "not constitute meaningful proof of [defendants'] weight loss claims"); *see also* Federal Trade Commission, "Dietary Supplements: An Advertising Guide for Industry," http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm ("Anecdotal evidence about the individual experience of consumers is not sufficient to substantiate claims about the effects of a supplement. Even if those experiences are genuine, they may be attributable to a placebo effect or other factors unrelated to the supplement. Individual experiences are not a substitute for

scientific research."). Of course, the value of these individual case reports are also suspect because it is not known (and not disclosed in the advertisements) whether these consumers also took other steps to lose weight or whether they kept the weight off. The Order requires competent and reliable scientific evidence and does not countenance substantiation through mere anecdote. Because defendants and Ehrman cannot substantiate this efficacy claim, they have violated Paragraph III of the Order.

B. THE COURT SHOULD IMPOSE SANCTIONS ON ENFORMA TO COERCE COMPLIANCE WITH THE ORDER AND TO COMPENSATE PAST VIOLATIONS

District courts are afforded wide discretion in determining appropriate sanctions for civil contempt. *McGregor v. Cherico*, 206 F.3d 1378, 1385 n.5 (11th Cir. 2000). Sanctions in civil contempt serve two purposes – to coerce the defendant into compliance with the Court's order and to compensate for losses sustained as a result of the contumacious behavior. *FTC v. Productive Marketing, Inc.*, 136 F. Supp. 2d 1096, 1112 (C.D. Cal. 2001). Thus the Court may impose in its civil contempt citation an order awarding consumer redress based on the amount of gross sales of a product. *McGregor*, 206 F.3d at 1387-88. In this case, Enforma's past and continuing violations of the Order warrant stringent sanctions to cease its current violations and to provide remedial relief by compensating for prior infractions.

Since May 11, 2000, Enforma has disseminated many misleading and unsubstantiated claims in violation of the Order. For example, Enforma has claimed, in various ways, that Fat Trapper is clinically proven to trap fact and that Exercise In A Bottle stimulates metabolism, even while resting. Even though Enforma had no scientific substantiation for any of these claims, it went on to advertise that the products may be more effective when used together. Although Enforma has, after repeated inquiries by the Commission, discontinued making

some of these claims, contempt sanctions are nevertheless available to compensate for injuries incurred during the period in which defendant failed to comply with the Order. *See Cancer Research Inst., Inc. v. Cancer Research Society, Inc.*, 744 F. Supp. 526, 530-31 (S.D.N.Y. 1990). Most of Enforma's unsubstantiated advertising claims were only recently discontinued, while other claims continue to the present. Therefore, as a sanction for defendants' and Ehrman's contempt, the Commission requests that all revenues from the sales of Fat Trapper Plus and Exercise In A Bottle from May 11, 2000 to the date of full Order compliance be turned over to the Commission for consumer redress. This relief represents the ill-gotten gains from consumers' "tainted" purchase decisions, due to unsubstantiated and misleading advertising of the products in the face of a clear court order. *FTC v. Gill*, 2001 WL 1301218, at *12 (C.D. Cal., July 13, 2001), *appeal filed*, Sept. 6, 2001. Where consumers are induced to buy a product through deceptive means, a contempt sanction in the amount of gross sales of the product is appropriate. *McGregor*, 206 F.3d at 1388.[10]

Moreover, although Enforma has discontinued some of these claims, Enforma continues to call its product "Fat Trapper Plus," an express claim that its product "traps fat." As described above, Enforma has no competent and reliable scientific evidence that "Fat Trapper Plus" actually "traps fat." Thus, the very name of the product conveys an unsubstantiated and misleading claim. Trade name excision is a well-established remedy when the name itself conveys a

[10] In order to have a complete picture of Enforma's gross revenues, it is necessary to determine where the offending products were advertised and sold and what revenues Enforma derived from those sales. As discussed in greater detail in Section III.C. *infra*, Enforma has stymied the Commission's attempts to obtain this information as it relates to its post-Order advertising and sales outside the United States. Thus, one aspect of the relief the Commission seeks here is an order requiring defendants and Ehrman to provide this necessary discovery.

deceptive claim, and when less restrictive remedies, such as disclosures, are insufficient to eliminate the deception.[11] *See, e.g., Resort Car Rental System, Inc. v. FTC*, 518 F.2d 962, 964 (9th Cir. 1975) (affirming FTC order prohibiting as deceptive use of trade name "Dollar-A-Day" in connection with rental car agency).

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[11] Trade name excision is a longstanding and appropriate remedy to cure consumer injury caused by deceptive trade names. *See, e.g., FTC v. Algoma Lumber Co.*, 291 U.S. 67, 81, 54 S. Ct. 315, 321, 78 L. Ed 655, 664 (1934) (upholding FTC order excising word "white" from trade name "California White Pine" because lumber was made from inferior yellow pine); *Bakers Franchise Corp. v. FTC*, 302 F.2d 258, 262 (3d Cir. 1962) (upholding FTC order excising trade name "Lite Diet" in connection with bread that was lower in calories only because it was sliced thinner than other breads); *Carter Prods., Inc. v. FTC*, 268 F.2d 461, 497-99 (9th Cir. 1959) (upholding FTC order excising word "liver" from trade name, "Carter's Little Liver Pills" because pills were not found to have any effect on liver function); *Gold Tone Studios, Inc. v. FTC*, 183 F.2d 257, 259 (2d Cir. 1950) (upholding FTC order excising trade name "Gold Tone Studios" where photographic finishing process used by company was not the recognized gold tone process); *El Moro Cigar Co. v. FTC*, 107 F.2d 429, 431 (4th Cir. 1939) (upholding FTC order excising word "Havana" from trade name, "Havana Counts" cigars, despite written disclaimer that tobacco came from domestic sources); *FTC v. Army & Navy Trading Co.*, 88 F.2d 776, 780 (D.C. Cir. 1937) (upholding FTC order excising trade name "Army and Navy Trading Co." where few goods sold were army or navy goods); *Marietta Manufacturing Co. v. FTC*, 50 F.2d 641, 642 (7th Cir. 1931) (upholding FTC order excising trade name "Sani-Onyx, a Vitreous Marble" because product contained neither marble nor onyx); *Masland Duraleather Co. v. FTC*, 34 F.2d 733, 737 (3d Cir. 1929) (upholding FTC order excising trade name "Duraleather" because product not made of real leather); *Proctor & Gamble Co. v. FTC*, 11 F.2d 47, 48 (6th Cir. 1926) (upholding portion of FTC order excising word "naphtha" from various soap product trade names containing kerosene, not naphtha); *In re Brake Guard Prods., Inc.*, 1998 F.T.C. LEXIS 184 at *55-58 (Jan. 23, 1998) (barring the use of term "ABS" in connection with a brake product that was not an antilock braking system), *aff'd sub nom Jones v. FTC*, 194 F.3d 1317 (9th Cir. 1999).

In *Continental Wax Corp. v. FTC*, 330 F.2d 475 (2d Cir. 1964), the court affirmed the FTC's decision to bar a company from using the trade name "Six Month Floor Wax" to describe its product, when in fact, tests showed that the wax did not last for six months. The court noted that because including qualifying language on the label would only result in a confusing contradiction in terms, *e.g.*, "Six Month Floor Wax – Will not last and be effective for six months," no remedy short of complete excision of the trade name would suffice. *Id.* at 480. In this case, as in *Continental Wax*, any affirmative corrective disclosures would result in a contradiction in terms that would only further confuse consumers, *e.g.*, "FAT TRAPPER PLUS – Does not trap fat." Therefore, Enforma should be prohibited from using the name "Fat Trapper Plus" to convey an unsubstantiated claim.

Similarly, the trade name "Exercise In A Bottle" conveys that the product, when taken at the recommended dose, provides some of the health or weight loss benefits of exercise, such as increased metabolism. Paragraph I of the Order specifically prohibited Enforma from using product names such as "Fat Trapper," "Fat Trapper Plus," and "Exercise In A Bottle" to make such claims without competent and reliable scientific evidence. Nevertheless, Enforma continues to make these claims, and continues to blatantly violate this provision of the Order. Although Enforma will no doubt complain that it is being forced to cease using two trade names in which it has invested significant money and marketing efforts, this Court should not lose sight of the fact that these monies and efforts were expended purely to disseminate deceptive and unsubstantiated claims to an unsuspecting and susceptible public:

> Whatever value their trade name has come to acquire has therefore been due, in substantial measure, to its effectiveness as a vehicle for misrepresentation; and whatever investment [they] have made in that trade name has been hedged, in part, by the inducement of members of the public to purchase the product named under the mistaken belief that it will do that which it will not.

Continental Wax, 330 F.2d at 480. Therefore, the appropriate and justified remedy for Enforma's conduct is to prohibit the use of the trade names "Fat Trapper," "Fat Trapper Plus," or any variation thereof for its chitosan-based product, and the trade name "Exercise In A Bottle" or any variation thereof for its pyruvate-based product, unless and until it can provide competent and reliable scientific evidence supporting the claims therein.[12]

C. DEFENDANTS AND EHRMAN SHOULD BE REQUIRED TO RESPOND TO DISCOVERY REQUESTS CONCERNING THE POST-ORDER ADVERTISING AND SALE OF THE ENFORMA SYSTEM OUTSIDE THE UNITED STATES

As part of its efforts to present the Court with the full scope of Enforma's post-Order advertising, promotion, offering for sale and sale of and revenues from the Enforma System, Fat Trapper, Fat Trapper Plus and Exercise In A Bottle, the Commission sought to elicit discovery of these facts as they pertain to advertising, sales and revenues outside the United States after May 11, 2000. Defendants have objected to and refused to answer many of these discovery requests. For example, when requested to admit that "Enforma Natural or its authorized licensees caused the first Enforma infomercial to be broadcast on television after May 11, 2000 outside the United States," Enforma wrote that it "objects to this request on the ground that it calls for irrelevant information." Exh. 11, No. 62. Enforma asserted identical objections to numerous other requests for admission on this subject. *See id*. RFA Nos. 63-71, 121-42. Defendants' blanket objection is without merit and should be rejected.

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[12] As a logical extension of an order to excise the trade names "Fat Trapper" and "Exercise In A Bottle," the Court should also order that any products bearing these names presently in the distribution or retail chain be recalled so that these unsubstantiated claims are no longer disseminated to the public.

In the related *Garvey* case, the defendants there (represented by the same attorneys as are defendants and Ehrman here) also refused to respond to the Commission's discovery requests pertaining to the advertising and sale of and revenues from the Enforma System, Fat Trapper and Exercise In A Bottle outside the United States. The Commission filed a motion to compel that discovery and a hearing was held before U.S. Magistrate Judge Woehrle, the same magistrate judge assigned to this case. Judge Woehrle considered the extensive briefs presented by the parties, heard oral argument, granted the Commission's motion and required the *Garvey* defendants to respond to this discovery. Exh. 12. Despite this ruling, defendants here refuse to provide this discovery.

As Judge Woehrle held, the standard employed for determining whether recipients must respond to discovery requests regarding their activities outside the United States is not whether the FTC has extraterritorial jurisdiction. Rather, the question is whether discovery regarding the advertising, promotion, and sale of the Enforma System outside the United States is "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Under this broad scope of discovery, Judge Woehrle held that the Commission is entitled to discover whether the Enforma System was advertised or promoted outside of the United States, where, when, how often, and how much money was paid to Enforma as a result of sales generated in those countries.

Even under a more stringent standard for discovery than Rule 26(b)(1), the FTC is entitled to discovery on the extent to which the Enforma System was advertised, promoted or sold outside the United States. The FTC Act clearly authorizes the Commission to exercise its enforcement authority over deceptive sales made by domestic entities to consumers in foreign countries. Section 5 of the FTC Act gives the Commission authority to prohibit "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). "Commerce" is

defined in Section 4 of the FTC Act to include "commerce . . . with foreign nations." *Id*. § 44. The Order at issue in this case contains absolutely no limitations on its geographic scope and, in fact, adopts a finding that "[t]he acts and practices of the defendants were or are in or affecting commerce, as 'commerce' is defined in Section 4 of the FTC Act, 15 U.S.C. § 44." *See* Exh. 1 at 2 (finding no. 3). "[B]usiness dealings . . . with customers in foreign countries is foreign commerce within the meaning of the Constitution and the [FTC] Act." *Branch v. FTC*, 141 F.2d 31, 34 (7th Cir. 1944). Several courts have agreed that the FTC has jurisdiction over unlawful practices directed to foreign consumers under the FTC Act. *See, e.g., id; FTC v. Commonwealth Mktg. Group, Inc.*, 72 F. Supp. 2d 530, 545 (W.D. Pa. 1999) (finding offers for purchase and sales for foreign consumers were subject to the FTC Act); *FTC v. Skybiz.com, Inc.*, No. 01-CV-396-K(E) at 21 (N.D. Okla. August 31, 2001) ("The Court finds that the terms of this order may apply extraterritorially.") (Exh. 13.) Thus, advertising, promotion, and sales by defendants to consumers in foreign countries constitute "commerce" and are subject to enforcement action by the Commission. Discovery of such activities is relevant and permissible.

In their attempts to stymie this discovery, defendants and Ehrman apparently rely upon dictum in *Nieman v. Dryclean U.S.A. Franchise Co.*, 178 F.3d 1126 (11th Cir. 1999), for the proposition that the FTC Act does not apply extraterritorially. This reliance is misplaced.

First, unlike this case, the *Nieman* case did not concern a discovery dispute; it was a decision on the merits. As noted above, this distinction is important because the permissible scope of discovery under Rule 26(b)(1) is very broad.

Second, *Nieman* only decided the reach of the Franchise Rule, 16 C.F.R. § 436.1, in a private lawsuit brought by a disappointed *foreign* franchisee whose

franchise was to be entirely outside of the United States. The Commission played no role in that litigation – not even as an amicus. The *Nieman* court observed that the language and history of the Franchise Rule made it clear that the FTC never intended that the Rule "protect franchisees in foreign countries." *Nieman*, 178 F.3d at 1131. Any question of the reach of the FTC Act is irrelevant to the holding in *Nieman*, and the court's discussion of it is purely dictum.

Third, the reasoning behind *Nieman*'s discussion of the FTC Act is flawed. The *Nieman* court analogized the FTC Act to Title VII of the Civil Rights Act of 1964, which the Supreme Court held did not apply extraterritorially in *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244 (1991). However, the language of Title VII, unlike the FTC Act, did not explicitly cover commerce with foreign nations and is therefore not analogous. More analogous to the FTC Act is the Securities and Exchange Act of 1934, which defines commerce as commerce "among the several States, or between any foreign country and any State . . . ." 15 U.S.C. § 78c(a)(17). Cases interpreting the Securities and Exchange Act of 1934 have held that that statute has extraterritorial reach. *Alfadda v. Fenn*, 935 F.2d 475 (2d Cir. 1991); *Psimenos v. E.F. Hutton & Co.*, 722 F.2d 1041 (2d Cir. 1983); *SEC v. Briggs*, 234 F. Supp. 618 (N.D. Ohio 1964). Indeed, in *Leslie v. Lloyds of London*, 1995 U.S. Dist. LEXIS 15380 at *53-55 (S.D. Tex. Aug. 28, 1995), the court explicitly distinguished *EEOC* and held that the definition of "commerce" under the Securities Exchange Act of 1934 includes the extraterritorial application of that statute.

Finally, even if the reasoning of *Nieman* is correct, its facts are distinguishable. While *Nieman* involved an international dispute brought by a foreign party, this case involves a dispute between the FTC and U.S. citizens. Unlike the *Nieman* case, in this case the plaintiff (the Commission), defendants Enforma and Grey, and Ehrman are all located in or are citizens of the United

States residing in the United States. Thus, it is difficult to imagine how the Commission's efforts to obtain *discovery* into matters surrounding these royalty payments runs afoul of *Nieman*.

In *Branch v. FTC*, 141 F.2d 31 (7th Cir. 1944), the Seventh Circuit upheld a Commission order against a mail order correspondence school that catered to residents of Latin American countries. It reached its decision that the petitioner was subject to the Commission's jurisdiction despite the facts that "much of the objectionable activity occurred in Latin America." *Id*. at 34. Depending on what discovery yields on the matters at issue here, the facts in this case may be similar to those of the *Branch* case.

For all the foregoing reasons, defendants and Ehrman's assertion that the Commission lacks jurisdiction to obtain this discovery is without merit. In order to have all the information required to effect complete relief of defendants and Ehrman's contempt, the Court should compel full and complete answers to the Commission's discovery requests on these subjects.

IV. CONCLUSION

For the foregoing reasons, the Commission respectfully requests that the Court issue an Order to Show Cause why defendants Enforma Natural Products, Inc. and Andrew Grey and Enforma Vice President Michael Ehrman should not be held in civil contempt for violating the Stipulated Final Order and Settlement of Claims for Monetary Relief as to Defendants Enforma Natural Products, Inc. and Andrew Grey. Defendants and Ehrman should also be required to answer the Commission's discovery requests pertaining to their advertising and sale of and revenues from the Enforma System, Fat Trapper, Fat Trapper Plus and Exercise In A Bottle outside the United States after May 11, 2000.

Dated: January 3, 2002

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 3, 2002, a true and correct copy of the foregoing MEMORANDUM IN SUPPORT OF PLAINTIFF'S APPLICATION FOR AN ORDER TO SHOW CAUSE WHY DEFENDANTS ENFORMA NATURAL PRODUCTS, INC. AND ANDREW GREY AND NONPARTY MICHAEL EHRMAN SHOULD NOT BE HELD IN CIVIL CONTEMPT was served in the manner indicated on:

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