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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ENFORMA NATURAL PRODUCTS, INC. and ANDREW GREY,

Defendants

and

TWENTY-FOUR SEVEN, LLC and DONNA DiFERDINANDO,

Respondents.

CV 00-04376-JSL (CWx)

Hon. J. Spencer Letts

MEMORANDUM IN SUPPORT OF PLAINTIFF'S *EX PARTE* APPLICATION FOR AN ORDER TO SHOW CAUSE WHY DEFENDANTS ENFORMA NATURAL PRODUCTS, INC. AND ANDREW GREY AND RESPONDENTS TWENTY-FOUR SEVEN, LLC AND DONNA DiFERDINANDO SHOULD NOT BE HELD IN CIVIL CONTEMPT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND RELATED RELIEF

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I. INTRODUCTION

Plaintiff Federal Trade Commission ("Commission") hereby respectfully seeks a second Order to Show Cause in this case, along with a temporary restraining order and a preliminary injunction, to stop the systematic and ongoing dissemination of false and unsubstantiated advertising claims that are violative of the Stipulated Final Order and Settlement of Claims for Monetary Relief as to

and respondents are making unsubstantiated claims for Chitozyme and Acceleron.[1] As with the first civil contempt application, these ongoing unsubstantiated claims go to the very heart of the Order entered by this Court.

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[1] Defendants and respondents may also be making unsubstantiated claims concerning their Carb Trapper Plus products' purported ability to reduce hunger, appetite and cravings and to cause weight loss without reducing caloric intake or exercise. However, the Commission has been unable to analyze sufficiently defendants and respondents' purported substantiation for Carb Trapper Plus because they seriously delayed producing the relevant data that underlies the main study relied upon and they continue to refuse to provide documents concerning their communications with the author of that study. If, after analysis, the Commission determines that claims for Carb Trapper Plus are also unsubstantiated, it will file a supplemental contempt application requesting appropriate findings and relief.

first disseminated to the public (after May 11, 2000); and (2) compensate the Commission for its expenses in bringing and pursuing this application. A proposed second order to show cause, including a temporary restraining order, is lodged with this application.

II. STATEMENT OF FACTS

A. PROCEDURAL HISTORY

On January 4, 2002, the Commission filed its first application for civil contempt in this case. It was filed against defendants Enforma Natural and Andrew Grey and non-defendant Michael Ehrman. That application, which is pending, concerns defendants and Ehrman's post-Order advertising, promotion and sale of "Fat Trapper Plus" and "Exercise In A Bottle" and alleges that numerous claims (including those two trade names themselves) violate paragraphs I, III, and IV of the Stipulated Final Order.

In March 2002, the Court approved the joint recommendation of the parties to the first civil contempt proceeding and entered an Order Appointing David Heber, M.D., Ph.D. as the Court-Appointed Expert in that proceeding. The parties subsequently filed their separate lists of scientific issues that they felt the Court should submit to Dr. Heber for his examination, analysis and opinions. The Commission suggested eight issues and defendants and Ehrman suggested 18 issues. The docket in this case does not indicate that the Court has submitted anything yet to Dr. Heber for his review.

B. P O S T - O R

In May 2002, the Commission learned that two new infomercials, both hosted by Kevin Trudeau, are being broadcast on television in the United States for additional weight loss products formulated by defendants Enforma Natural and Grey or by entities and individuals associated with them. These dietary supplements are Chitozyme, Acceleron and Carb Trapper Plus. As described in

the "relationship diagram" that is attached to Frankel Decl. Ex. 2, two of these products, Acceleron and Carb Trapper Plus have been sold directly by Enforma Natural via its official Internet web site at www.enforma2000.com (Frankel Decl. Ex. 10) and at retail under the Enforma name (Frankel Decl. Exs. 17-18 (Rite Aid and CVS)). Acceleron and Carb Trapper Plus are also sold by 24/7, a California corporation having three general partners: Enforma Natural, Grey and Bonagenics, Inc., a Delaware corporation. *See* Frankel Decl. Exs. 3 and 4. Defendant Grey is listed as the CEO of 24/7 and is also the President of Bonagenics. Thus, defendant Grey appears to be the common thread connecting Enforma Natural with 24/7. *See id*. The other product at issue in this second civil contempt application, Chitozyme, does not appear to have been marketed under Enforma Natural's name, but only by 24/7. However, counsel for defendants and respondents have informed the Commission that the product formula for Chitozyme is exactly the same as the formula for Fat Trapper Plus,[F0]

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[2] *I.e.*, 350 mg of chitosan and 50 mg of psyllium husks. *See* Frankel Decl. Ex. 14.

[3] Because the Internet web site that advertises Chitozyme, Acceleron and Carb Trapper Plus in combination is purported to be affiliated with 24/7 and these are the same products respondent DiFerdinando touts in the two infomercials, it is reasonable to conclude that respondent DiFerdinando is the Vice President for

DiFerdinando: It's – it's chitosan, which is a natural fiber and it helps to trap fat. And when you're trapping fat, you're losing weight. So, it's just an added bonus.

Trudeau: And there's some research, also, on chitosan, if you take it to lose weight?

DiFerdinando: De researcCp fat and24
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[5] The 24/7 web site describes Chitozyme as "a revolutionary fat trapping product that promotes weight loss while letting you still eat your favorite foods guilt free!" *See* Frankel Decl. Ex. 12. Similarly, the label for Chitozyme contains a section titled, "**SCIENTIFIC PROOF**" which states in part:

> Scientific experts have been studying chitosan's ability to trap fat and help promote weight loss for almost a decade. More than 15 human studies, animal studies and in vitro studies exist indicating that chitosan, the main ingredient in Chitozyme has the ability to trap fat, promote weight loss and/or help maintain healthy cholesterol levels.

See Frankel Decl. Ex. 13 (emphasis in original).

[6] It is well established that the court evaluates the net impression created by the totality of the advertisement and not just any one isolated phrase or element. *See FTC v. Sterling Drug* *FTC, 317 F.2d 669, f 4asi2d Ciremp963)asim on*

2. <u>Claims For Acceleron</u>

a. Unsubstantiated efficacy claims

In the first infomercial, show host Trudeau and the purported product developer, DiFerdinando, engaged in the following colloquy concerning the purported proven efficacy of Acceleron:

(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 its 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 RESPONDENTS' CIVIL CONTEMPT

1. <u>Defendants And Respondents Are Bound By A Valid, Effective Order</u>

The Order entered by this Court on May 11, 2000 is a valid court order that requires defendants and respondents 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). Given defendants Enforma Natural and Grey's role in 24/7, and 24/7's role in selling Chitozyme and Acceleron, 24/7 is clearly in active concert with defendants. Likewise, respondent DiFerdinando is employed by defendant Enforma Natural and is therefore in active concert with it. On September 19, 2000, DiFerdinando acknowledged that she was a person having responsibilities with respect to the subject matter of the Order and that she received a copy of the Order within the prescribed time frame. *See* Frankel Decl. Ex. 23.[8] As Enforma's Director of Marketing and as a star in both infomercials, she clearly is in active concert or participation with defendants Enforma and Grey with actual notice of the Order and its terms. Thus, she is also bound by the Order.

2. <u>The Order Requires Certain Substantiation And Prohibits Certain Misrepresentations By Defendants And Respondents</u>

Paragraph I of the Order specifically enjoins defendants and respondents from disseminating certain specified express or implied claims unless they possess "competent and reliable scientific evidence that substantiates the representation[s]." Frankel Decl. Ex. 1 (Order ¶ I).[9] The express and implied

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

[9] "Competent and reliable scientific evidence" is defined in the Order to mean "tests, analyses, research, studies, or other evidence based on the expertise

claims covered by Paragraph I include claims that the products (a) enable consumers to lose weight, avoid weight gain or maintain weight loss without the need for a restricted calorie diet or exercise; (b) prevent the absorption of fat in the human body; (c) increase 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) enable consumers to lose weight even if consumers eat foods high in fat, including fried chicken, pizza, cheeseburgers, butter, and sour cream. *Id*.

Paragraph II of the Order enjoins defendants and respondents from advertising that their products enable consumers to lose weight, avoid gaining weight or maintain weight loss unless they disclose clearly and prominently that reducing caloric intake and/or increasing exercise is required to lose weight. *Id*. ¶ II. This provision further requires that in video ads of fifteen minutes or longer, the required disclosure must be displayed within the first 30 seconds of the ad and immediately before each presentation of ordering instructions for the product. *Id*. ¶ II.C.

Paragraph III of the Order enjoins defendants and respondents from disseminating express or implied representations concerning weight loss benefits, performance or efficacy of certain 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 respondents from "misrepresenting, in any manner, expressly or by implication, the existence,

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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." *See* Frankel Decl. Ex. 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.

contents, validity, results, conclusions or interpretations of any test, study, or research." *Id.* ¶ IV.

3. Defendants And Respondents Failed To Comply With The Order

Defendants and respondents have blatantly ignored the core conduct provisions of the Order by: (a) ignoring Paragraph II of the Order and failing to display in the two new infomercials the required disclosure that reduced caloric intake or increased exercise is required to lose weight; (b) making numerous unsubstantiated claims for their newer products, Chitozyme and Acceleron; and (c) misrepresenting the results of studies. These flagrant, consistent and pervasive transgressions of the Order have caused, and will continue to cause, additional monetary injury to vulnerable consumers who seek the elusive miracle pill that will permit them to enjoy calorie-laden foods without experiencing the weight gain that such foods typically cause.[10] Defendants and respondents persist

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[10] 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, and had risen to an estimated $117 billion in 2000 ($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 using express and strongly implied claims to continue to spread the same messages that led to the original Order – that with Chitozyme, consumers can eat fatty foods without fear that the fat will be absorbed by the body and lose "a lot of weight," and that with Acceleron, consumers can increase their metabolism and thereby lose weight.

a. Defendants and respondents have failed to include the Court-ordered disclosure into the two new infomercials

Paragraph II of the Order enjoins defendants and those in active concert or participation with them from advertising that a product enables consumers to lose weight, avoid gaining weight or maintain weight loss unless they disclose clearly and prominently that reducing caloric intake and/or increasing exercise is required to lose weight. This provision further requires that in video ads of fifteen minutes or longer, the required disclosure must be displayed within the first 30 seconds of the ad and immediately before each presentation of ordering instructions for the product.[11]

Despite this very clear Order provision, neither of the two new

[11] The mere addition of the specified disclosure at the intervals required by the Order would not change the net impression that the advertised products cause weight loss without diet or exercise. The numerous references to the ability to eat the foods that consumers "enjoy," "want," or "usually" eat, the repetition of those foods by name, and the touted lack of any need to exercise creates an overwhelming net impression that diet and exercise are not required.

b. Defendants and respondents have no competent and reliable scientific evidence supporting their claims that Chitozyme traps fat in the human body

In its January 4, 2002, first application for civil contempt, the Commission filed two declarations from its outside expert, David Levitsky, Ph.D., a professor in the Division of Nutritional Sciences and the Department of Psychology at Cornell University. Those declarations discussed in detail Dr. Levitsky's opinion that defendants possessed no competent and reliable scientific substantiation for the claim that Fat Trapper Plus trapped or absorbed fat in the human body. Since Chitozyme is identical to Fat Trapper Plus, the Commission incorporates and relies upon those two declarations (Docket Nos. 42, 53) as its primary evidence that the identical claim for Chitozyme is likewise unsubstantiated.

In the interim, counsel for defendants have provided the Commission with one additional study of Fat Trapper Plus that purports to show that consumption of that product, in dosages higher than most consumers would likely consume,[12] results in increased fat absorption as measured by fecal fat excretion. However, it is Dr. Levitsky's opinion that this new study was ineptly reported, improperly conducted, in that it excluded data from some subjects who completed the study, and incorrectly statistically analyzed. Levitsky Decl. ¶¶ 4-6. In fact, when properly analyzed, the data do not show the statistical significance required for scientists to conclude that the treatment had any effect. *See id.* at ¶ 5. This newly-produced study neither refutes nor undercuts the results of the two previous fecal fat studies of Fat Trapper Plus that failed to show the product had

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[12] The tested dosage was six capsules prior to each of three daily meals. Levitsky Decl. Ex.1. The Fat Trapper Plus package recommends taking three to six capsules prior to "eating any high-fat meals." Thus, unless consumers *both* eat three high-fat meals daily and take the maximum dose each time, this study tested a higher dosage than consumers will consume.

[13] In this connection, even if the newly produced Fat Trapper Plus fecal fat study (Levitsky Decl. Ex. 1) was properly conducted and analyzed, Dr. Levitsky calculated that it showed a reduction of only an additional 3.1 grams of fat absorbed each day. At that rate, it would take approximately 125 days to lose one

[15] The published literature contains one other double-blind chitosan weight loss study in which subjects were not placed on a restricted calorie diet. *See* Levitsky Decl. ¶¶ 12-15. That study failed to present a statistical analysis of the difference in weight loss between the chitosan and placebo groups, thereby making it inconclusive regarding the effect, if any, of chitosan in that study. *See id.* ¶ 12. Additionally, one of the statistical analyses that was presented was wrong, the reported data was internally inconsistent, and the data showed that the chitosan group, on the whole, did not lose any fat. *Id.* ¶¶ 12-14. Accordingly, this study provides no reliable data supporting the challenged Chitozyme weight loss claim. *Id.* at 14. Likewise, the remaining studies defendants have relied upon as support for this weight loss claim are seriously flawed and do not constitute a scintilla of competent and reliable scientific substantiation for that claim. *See id.* ¶¶ 16-20. In fact, two of those studies were not double-blind, placebo-controlled studies. *See id.* ¶¶ 16-17, 19-20.

The courts have held that double-blind, placebo-controlled studies are required to provide adequate substantiation for advertising claims, including claims for dietary supplements. *See, e.g., FTC v. Pantron I Corp.*, 33 F.3d 1088, 1097-98 (9th Cir. 1994) (placebo-control required for hair growth product); *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1500 (1st Cir. 1989) (double-blind studies for cosmetic hair removal treatment);

Lastly, defendants have proffered as substantiation a group of studies that test chitosan in a manner that is totally contrary to the way they market Chitozyme. Specifically, they rely upon studies that test chitosan taken in conjunction with severely restricted calorie diets ranging from 950 to 1200 calories per day, and assert that such results show what happens when consumers take Chitozyme without varying from their normal diet. That extrapolation does not constitute competent and reliable scientific evidence of the effect that will occur on non-dieting consumers because the human body responds metabolically differently when placed on a restricted calorie diet. Levitsky Decl. ¶ 21. Thus, none of these studies can substantiate the challenged weight loss without dieting claim. *Id*.

The published studies in this *genre* were all published in one Italian journal, and are missing such fundamental data or contain such fundamentally unsupported conclusions as to raise serious questions regarding whether the journal is even peer reviewed.[16] *See* Levitsky Decl. ¶¶ 22-27. Moreover, four of the six published articles failed to report the most fundamentally important data, the dosage of chitosan given the subjects. Without such data, a scientist cannot tell if the dosage was similar to the chitosan content of Chitozyme or many times greater. *See id.* at ¶ 23. This flaw alone renders them incapable of scientifically

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substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. California Pac. Research, Inc.*, 1991-2 Trade Cas. (CCH) ¶ 69,564 at 66,503 (D. Nev. 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability").

[16] The Cornell University library could not locate this journal on any list of peer reviewed scientific journals. Levitsky Decl. ¶ 22.

substantiating the Chitozyme weight loss claim at issue here.[17] *Id.* These studies are otherwise flawed as well, and in toto, cannot scientifically substantiate defendants and respondents' Chitozyme substantial weight loss without diet claims.[18] *See id.* at ¶¶ 21-28. In short, although defendants and respondents may point to studies of chitosan, those studies either fail to report a weight loss effect, are severely flawed, or test chitosan under inapplicable conditions, and, as such, cannot constitute scientific substantiation for the challenged weight loss claim.

Because defendants and respondents have made unsubstantiated claims that Chitozyme allows consumers to lose weight without the need to diet or exercise, they have violated Paragraphs I and III of the Order.

d. Defendants and respondents have no competent and reliable evidence that Acceleron increases metabolism

In the challenged advertising, Acceleron is repeatedly touted as a pill that has been "proven" to "speed up" metabolism and "burn more calories." Metabolism is related to weight loss, and when a product is touted as "increasing metabolism," consumers understand that this product is promising weight-loss. Indeed, "increasing metabolism" merely describes the mechanism of action by

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[17] The remaining two Italian studies gave chitosan dosages but failed to provide a statistical analysis of the difference in weight loss between the chitosan and placebo groups. Levitsky Decl. ¶¶ 24-26. The omitted statistical analysis is the only one that would constitute scientifically valid evidence regarding whether the chitosan actually caused an effect. *Id.* ¶ 25.

[18] Defendants have submitted three other unpublished chitosan weight loss studies that employ various forms of restricted calorie diets as well. Dr. Levitsky opines that all are either flawed, fail to report statistically significant results, or are so incomplete in their data reporting as to fail to provide any competent and reliable scientific evidence supporting the Chitozyme weight loss claim. *See* Levitsky Decl. ¶¶ 29-32.

which such a product will cause weight loss.[19] As discussed *infra*, there is no competent and reliable evidence that Acceleron causes weight loss, and as set forth below, there is no such evidence that Acceleron increases metabolism.

It is well-established that if one can significantly increase their metabolic rate and maintain that increased rate over time, the body will burn calories at an increased rate and it is likely that some weight loss will likely occur. *Id.* ¶ 45.

[19] The infomercials very clearly make this connection between increasing metabolism and burning more calories. *See, e.g.*, Frankel Decl. Ex. 7 at 6:1-11; Frankel Decl. Ex. 9 at 16:7 to 17:13.

inadequate to demonstrate that such intervention caused any measurable, overall metabolic change. *Id.* ¶ 49. Furthermore, this study is flawed because of the substantial differences between the active and placebo groups at baseline – the treatment group was nine pounds heavier, and the placebo group had a baseline metabolic rate that was over 220 calories per day higher than the active group. *Id.* ¶ 50.

The remaining studies relied upon by defendants and respondents for the metabolism claims are similarly flawed for the reasons set forth in detail in Dr. Levitsky's declaration. *Id.* ¶¶ 52-58. In summary, these studies measured metabolism over an insufficient period of time and failed to use adequate controls. Further, any difference in metabolism observed in the studies was clinically insignificant for purposes of weight loss, even if one were to assume that the effect would persist beyond the period measured.[20] *Id.* ¶ 56. Thus, despite defendants and respondents' claims, there is no reliable and competent evidence supporting the contention that Acceleron or its active ingredient increases metabolism, and they are in violation of Paragraphs I and III of the Order.

e. Defendants and respondents have no competent and reliable evidence that Acceleron causes weight loss

As discussed in Section II.B.2, *supra*, the net impression of the infomercials is that Acceleron causes weight loss without the need to diet or exercise. In fact, according to Dr. Levitsky's analysis of the studies relied upon by defendants and respondents, they have no reliable scientific evidence that Acceleron causes any weight loss. Levitsky Decl. ¶¶ 33 to 44. Of the five primary studies relied upon by defendants and respondents, only one analyzed

[20] The authors state that the clinical benefit remains to be demonstrated. Levitsky Decl. Ex. 14 at 00123.

body weight in humans.[21] As detailed in the Declaration of Dr. Levitsky, this study (the "Colker study") does not support weight loss claims for Acceleron. First, it used a dosage of active ingredient (citrus aurantium) that is much higher than that found in Acceleron and contained an ingredient that is not in Acceleron. Moreover, Acceleron contains several ingredients that were not in the test compound studied in the Colker study. It is not scientifically acceptable to draw conclusions about one product based on the results of a study of a second product when there are such differences between the active ingredients and their dosage. *Id.* ¶ 39. *See SlimAmerica*, 77 F. Supp. 2d at 1274.

[21] Another study relied upon by defendants and respondents looked at the antiobesity effects of Acceleron's active ingredient on rats. It is not directly relevant to the ability of Acceleron to cause weight loss in humans. Even if it could be extrapolated to humans, defendants and respondents fail to note that the rats given the product suffered a high rate of cardiovascular toxicity and death, ranging from 10-50%, depending on dosage.

[22] Earlier versions of the Acceleron packaging conceded that this study and others cited were only "preliminary findings." Such preliminary studies do not support the absolute effectiveness claims touted in the infomercials.

scientific conclusions about the efficacy of Acceleron when used as advertised in the infomercials.

This weight loss study – conducted on a product that differs substantially from Acceleron – does not constitute competent and reliable evidence that Acceleron causes weight loss. *See id.* ¶¶ 36-44. Defendants and respondents have therefore violated Paragraphs I and III of the Order.

f. Defendants and respondents have falsely claimed that clinical studies demonstrate that Acceleron causes weight loss

The most recent packaging for Acceleron states, *inter alia*, that the Colker study "showed that subjects using the main ingredients in Acceleron™ lost significantly more weight than subjects who did not." Frankel Decl. Ex. 15. This is a false statement for two reasons. First, as Dr. Levitsky explains, the Colker

defendants and respondents do not have such competent and reliable scientific evidence. Defendants and respondents are therefore unable to sustain their Court-ordered burden. Taken together, this evidence demonstrates that the Commission is likely to succeed on the merits of its contempt application.

b. There is a possibility of irreparable harm

When the Commission seeks temporary or preliminary relief pursuant to the Federal Trade Commission Act, courts presume that irreparable harm has occurred because passage of the statute is deemed to be an implied finding by Congress that violations will harm the public. *See, e.g., FTC v. World Wide Factors, Ltd.*, 882 F.2d 344, 347 (9th Cir. 1989) ("irreparable injury must be presumed in a statutory enforcement action"); *Arlington Press*, 1999-1 Trade Cas. (CCH) ¶ 72, 415, at 83,888, *quoting Miller*, 19 F.3d at 459. This contempt application is based on a Court Order that was itself grounded on enforcement of the FTC Act. When the Court entered its May 2000 Order, it expressly stated: "Entry of this Order is in the public interest." *See* Order at 2 (finding number 8). Therefore, as with a direct violation of the FTC Act, any violation of the Order should also be presumed to cause irreparable harm.

Nevertheless, consumers suffer two types of injuries as a result of defendants and respondents' unsubstantiated advertising. First, there is the direct economic injury that arises from purchasing these products. No matter how meticulous defendants and respondents' records are, it will be impossible to locate and reimburse each and every purchasing consumer. This is especially true for consumers who purchase Acceleron at retail – there will likely be no records available to identify such consumers, let alone calculate how much each individual spent. As one appellate court has held, "[t]he threat of unrecoverable economic loss . . . does qualify as irreparable harm." *See Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996).

Second, consumers are injured to the extent that they purchase these products as a substitute for other treatments that may offer them real health benefits. So, for example, purchasers of Chitozyme or Acceleron may forego making such lifestyle changes as reducing their caloric intake or beginning an exercise program as, indeed, the infomercials assure can be foregone, so long as the advertised products are consumed. This decision can cause irreparable harm to consumers' health – especially to a group of consumers that is likely to be overweight or obese, and therefore subject to the serious health consequences that are associated with these conditions. These adverse health consequences include 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. *See* note 10 *supra*.

In the context of comparative advertising claims, it is well-established that there is a presumption of irreparable harm for false or misleading advertising claims. *McNeilab, Inc. v. American Home Prods. Corp.*, 848 F.2d 34, 38 (2d Cir. 1988) ("the district court did not err in presuming harm from a finding of false or misleading advertising"); *Valu Eng'g v. Nolu Plastics, Inc.*, 732 F. Supp. 1024, 1025 (N.D. Cal. 1990) ("[I]n cases of false comparative advertising, irreparable harm is presumed."); *see also Castrol, Inc. v. Pennzoil Co.*, 799 F. Supp. 424, 440 (D.N.J. 1992) (in evaluating irreparable injury, court was "cognizant of the compelling public interest to protect competitors and consumers from false commercial advertising claims.").

Thus, absent immediate relief, there is a strong possibility that purchasing consumers will irreparably suffer both direct economic injury and adverse health consequences.

c. The balance of hardships weighs in the Commission's favor

The Commission has never taken the position that defendants and respondents are prohibited from *selling* these products (or any other dietary supplements). Rather, the Commission is merely seeking to prevent the dissemination of false and unsubstantiated advertising, packaging and labeling claims to the public. If defendants and respondents wish to promote these products using different claims, they may do so, provided that they abide by this Court's Order and maintain competent and reliable substantiation for those claims. The Commission has always stood ready to work with defendants and respondents to evaluate or provide advice with respect to potential claims, but they have never sought the Commission's (or the Court's) guidance. In fact, warnings by the Commission that certain claims appeared to violate the Order have been ignored and the unsubstantiated advertising has continued or has become even more strident.[24]

This contempt application should not be viewed in a vacuum. In January 2002, the Commission filed its first contempt application against defendants and Michael Ehrman and raised issues that are similar to those presented here, albeit for the products Fat Trapper Plus and Exercise In A Bottle. In its first contempt application the Commission did not seek preliminary injunctive relief, despite the

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[24] For example, even before it learned of the existence of the latest infomercials, the Commission put Enforma and Grey on notice that it believed that the same claims – which were being made on the Internet and on product packaging – were unsubstantiated. On April 23, 2002, the FTC sent Enforma and Grey's counsel a letter expressly stating that claims that Acceleron "cause[d] weight loss" or "increase[d] metabolism" were "not substantiated by competent and reliable scientific evidence." Frankel Decl. Ex. 21. And on April 26, 2002, the Commission sent a more detailed follow-up letter explaining some of the reasons why these claims were unsubstantiated. *Id.* Ex. 22. Tellingly, in this letter, the Commission also reminded Enforma and Grey's counsel of the "diet and exercise" disclosure requirement in Paragraph II of the Order. *Id.*

fact that some of the challenged claims were ongoing. Although the first contempt application remains pending, defendants and respondents have apparently taken this as a license to make new, unsubstantiated advertising, packaging and labeling claims for new products. Certainly, defendants and respondents did this knowing the risks they face being held in contempt of the Order.

In *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 129 F. Supp. 2d 351, 369 (D.N.J. 2000), *aff'd*, 290 F.3d 578 (3d Cir. 2002), the district court entered a preliminary injunction that, *inter alia*, enjoined Johnson & Johnson from "claiming, either explicitly or implicitly, in any packaging, advertising, or other promotional materials, that Mylanta Night Time Strength is specially formulated for night time heartburn, provides all night relief, and/or possesses a strength that correlates with its efficacy." The broad preliminary injunction in that case, which also prohibited the further marketing of the product trade name, was affirmed in its entirety by the Third Circuit. In addressing the balance of the harms element in its decision, the appellate court stated that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought the injury upon itself." 290 F.3d at 596. Like Johnson & Johnson, defendants and respondents in this case have also "brought the injury upon" themselves.[25]

[25] The appellate court in *Novartis* was also persuaded that because the preliminary injunction did "not prohibit J&J from shipping the product currently in inventory under a different name, label and advertising," this reduced the harm it suffered under the injunction. *See* 290 F.3d at 597. The Commission has been careful to craft the proposed injunction here to specifically permit defendants and respondents to disseminate and sell Chitozyme and Acceleron with new packages and labels that contain none of the violative claims. *See* Proposed Order ¶ II.

If preliminary injunctive relief is not granted here and the Commission ultimately prevails on the merits, the Commission will likely be unable to provide redress to thousands of injured consumers for the monies they continue to pay to purchase products bearing false and unsubstantiated claims on their packaging and labeling. Instead, most recovered revenues will likely have to be disgorged to the U.S. Treasury. Thus, any costs that accrue to defendants and respondents from having to stop disseminating the two new infomercials, having to change their Internet web sites, and having to recall product packaging and labeling should be outweighed by the fact that consumers who purchased Chitozyme and Acceleron on the basis of unsubstantiated claims, will likely never be made whole.

d. The requested relief is in the public interest

The provisions of the Order that the Commission is seeking to have enforced are clear and concern the core conduct that was meant to be proscribed. Certainly, both the public and the Court have an overarching interest in ensuring that core order provisions relating to dietary supplements are enforced vigorously and fairly.

As an agency charged by statute with promoting the public interest, the Commission is acutely aware of the effects unsubstantiated advertising has on unsuspecting consumers of dietary supplements, on sellers of competing products or services that offer legitimate remedies, and on the overall marketplace for health-related goods and services – since deceptive advertising devalues all legitimate advertising.

The public interest is served by the proposed Order requiring the immediate cessation of the dissemination of the two new infomercials, the immediate cessation of certain claims on defendants and respondents' Internet web sites, and the immediate recall or relabeling of product packaging and labeling containing false and unsubstantiated claims, for the following reasons. First, those under

Court order need to understand that they cannot flout those orders with impunity. Second, the requested order will, if entered, validate, reinforce and provide additional substance to the competent and reliable scientific evidence standard set out in this Court's May 2000 Order. Third, an immediate injunction will greatly reduce the direct economic injuries suffered by consumers who would otherwise see or read false and unsubstantiated claims and purchase Chitozyme and Acceleron on the basis of deception. Fourth, it will reduce the natural tendencies of consumers to seek a magic pill to solve their problems with overweight or obesity and may result in a shift towards proven remedies of reduced caloric intake and exercise. Fifth, it will help promote consumers' beliefs that advertised claims for health-related products are based on some measure of substantiation.

The Ninth Circuit and other courts have found that "the public has a particularly strong interest in an accurate description of health and medical products." *Jarrow Formulas, Inc. v. Nutrition Now, Inc*., No. 01-55154 2002 WL 1163624, at *10 (9th Cir. June 4, 2002) (*citing Conopco, Inc.v. Campbell Soup Co.*, 95 F.3d 187, 194 (9th Cir. 1996) ("We have consistently held that the public's interest is especially significant when health and safety concerns are

prosecuting this contempt application. *See, e.g., Hutto v. Finney*, 436 U.S. 678, 690, 98 S. Ct. 2565, 2573, 57 L. Ed. 2d 522, 534 (1978);

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 respondents 24/7 and DiFerdinando 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. As part of this relief, the Commission further respectfully requests that the Court enter a temporary restraining order, followed by a preliminary injunction, prohibiting the further dissemination of further unsubstantiated claims presently being made through various media, such as via television infomercials, Internet web sites, and on product packaging and labeling.

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Respectfully submitted,

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