



April 7, 2016

VIA OVERNIGHT MAIL AND EMAIL

Jessica Rich, Director, Bureau of Consumer Protection
Mary Engle, Associate Director, Division of Advertising Practices
Federal Trade Commission
600 Pennsylvania Ave. N.W.
Washington, D.C. 20580



John D. Jacobs
FTC Western Region, Los Angeles
10877 Wilshire Blvd., Suite 700
Los Angeles, CA 90024



Re: Violations of Stipulated Final Judgment and Order in
FTC v. FiberThin, LLC et al, Case No. 05-cv-1217, S. D. CA.

Dear Ms. Rich, Ms. Engle, and Mr. Jacobs:

As you may recall, the Federal Trade Commission filed suit against Obesity Research Institute, LLC and others in 2005 in the Southern District of California for their alleged deceptive marketing of certain dietary supplements.¹ That lawsuit resulted in a Stipulated Final Judgment and Order (“Order”) that prohibits Obesity Research Institute and the other defendants from making a number of marketing claims about their products.² Truth in Advertising, Inc. (TINA.org) has found evidence to indicate that Obesity Research Institute is currently violating this Order in several ways.³

To briefly summarize key provisions of the Order, all of the defendants are permanently prohibited from:

- (1) claiming that any product containing the active ingredient glucomannan (a) causes rapid or substantial weight loss, or enables users to lose 8 pounds or more per month, without the need to reduce caloric intake or increase physical activity, or (b) works for all users;⁴

- (2) claiming that any weight loss product or dietary supplement, regardless of active ingredients, (a) causes weight loss without the need to reduce caloric intake or increase physical activity, (b) increases metabolism, (c) has any health-related benefits, or (d) is safe and does not have any side effects, without having competent and reliable scientific evidence to substantiate such claims;⁵ and
- (3) misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study.⁶

Obesity Research Institute is currently violating each of these provisions. Specifically, the company now markets a weight-loss supplement called Lipozene, which contains the active ingredient glucomannan, and is making the following marketing claims, among others, about the product:

- (1) **Causes Substantial Weight Loss Without Changing Lifestyle:** The following is a sampling of substantial weight loss claims made by Obesity Research Institute:

Lipozene Television Commercials:

“If you want to lose 4X more weight doing exactly what you’re doing, whether your [sic] dieting, not dieting, working out, or not working out...don’t change what you’re doing! Just add Lipozene! America’s #1 diet supplement. Lipozene can help you lose 400% more weight or your money back!”⁷



Screen shot from the Lipozene “Weight Loss Mountain” television commercial⁸



Screen shot from the Lipozene “1 Million Bottles Sold” television commercial⁹

Lipozene.com Home Page:



Lipozene.com Reviews Page:¹⁰

Javana ★★★★★
Inglewood, California
I used Lipozene for two months and lost 35lbs. I would simply take the pill 30 min before meals and move through my day. Now I am more fit and healthier than I have ever been. This product works so well that I have decided to continue the usage until I reach my goal weight of 40 more lbs.
Thank Lipozene!

Lisa Hutson ★★★★★
Eden, North Carolina
Thank you so much for your product. I tried other products with no results even with Sensa but when my sister suggested this product, I decided to try it and in 2 months have lost 25 lbs. I still have a long way to go but this is the only thing that has helped me. I am not able to walk to exercise due to having only half of my left foot and no weight bearing bone in that foot so lipozene has been a god sent. Again thank you so much.



Comments:

Congratulations, Lisa! Thanks for sharing.

Lipozene Customer Service

These types of claims, which are scattered throughout the company’s marketing of Lipozene, violate Sections I.A and I.B of the Order.¹¹

- (2) **Works for All Users:** Obesity Research Institute states that Lipozene “is guaranteed to help you lose weight or your money back,”¹² “can help you lose 400% more weight or your money back,”¹³ and “guarantees you will lose weight and body fat.”¹⁴ Such statements make the implied claim that Lipozene will work for everyone, in violation of Section I.C of the Order.
- (3) **No Known Side Effects:** Obesity Research Institute claims that there are “no known side effects when taking Lipozene ... as directed”¹⁵ when, in fact, the company is aware of at least one report that notes that glucomannan – the active ingredient in Lipozene – can cause diarrhea and abdominal discomfort.¹⁶ Such claims violate Section II.D. of the Order.
- (4) **Safe and Effective:** Obesity Research Institute claims that Lipozene is “Safe & Effective”¹⁷ when the company is aware of at least two reports that state that additional studies regarding the safety and efficacy of glucomannan – the active ingredient in Lipozene – are needed before it can be safely recommended.¹⁸ Accordingly, such claims violate Section II.D of the Order.

In addition to the company’s violations of the Order with respect to its marketing of Lipozene, Obesity Research Institute is also violating the Order through its marketing of the supplement MetaboUP PLUS.¹⁹ Specifically, the company claims that the individual ingredients in MetaboUP PLUS “work to increase energy and metabolism” but does not cite to any scientific evidence to substantiate these claims.²⁰ Accordingly, such claims violate Section II.C of the Order.

Additional False and Deceptive Marketing Issues

In addition to the company's violations of the Order, Obesity Research Institute may also be violating truth in advertising laws that were not at issue in the 2005 FTC lawsuit.

(1) Deceptive Negative Option Offer

Upon information and belief, Obesity Research Institute binds consumers to a negative option offer without first obtaining their informed and express consent.²¹ TINA.org was unable to find a single instance in which Obesity Research Institute notifies consumers of the alleged automatic recurring charges that ensue once placing an order for Lipozene, despite numerous complaints of recurring charges from consumers. If indeed the company does automatically enroll consumers in recurring charges, the failure to clearly and conspicuously disclose all material terms of the transaction before obtaining consumers' billing information, as well as the failure to obtain consumers' express informed consent before charging their accounts is a violation of the Restore Online Shoppers' Confidence Act, 15 U.S.C. § 8403.²²

(2) False "Made in the USA" Claims

In some of its marketing, Obesity Research Institute represents that Lipozene is "Made in the USA."



Screen shot captured from a current Lipozene commercial.²³

Such an unqualified Made in the USA claim, however, contradicts representations made in other Lipozene commercials, which state that the product is "Assembled in the USA,"²⁴ as well as information on the company's website. According to the Frequently

Asked Questions section of the website, Lipozene is actually “assembled in the USA with quality imported and domestic materials.”²⁵

Based on this information, any unqualified Made in the USA claims regarding Lipozene are false and in violation of the FTC Act.

For the foregoing reasons, TINA.org urges the FTC to reopen its investigation of Obesity Research Institute and take appropriate enforcement action.

If you have any questions or need further information, please do not hesitate to contact us.

Sincerely,



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Cc: Henny Den Uijl, Obesity Research Institute

¹ *FTC v. FiberThin, LLC*, No. 05-cv-1217 (S.D. Cal. June 14, 2005).

² Stipulated Final Judgment and Order for Permanent Injunction, Monetary and Other Equitable Relief, *FTC v. FiberThin, LLC*, No. 05-cv-1217 (S.D. Cal. June 17, 2005).

³ Other defendants may also be in violation of the Order. For example, Henny Den Uijl – one of the defendants in the 2005 action – is currently listed as the Agent for Service of Process for Obesity Research Institute, LLC on the California Secretary of State’s website. *See* <http://kepler.sos.ca.gov/>.

It is also worth noting that in March 2016, a class-action lawsuit was filed against Obesity Research Institute and others in the Southern District of California alleging, among other things, that the company falsely markets Lipozene and is violating the 2005 Order in the *FTC v. FiberThin* case. *See Bozic v. Den Uijl, et al.*, Docket No. 16-cv-733 (S.D. Cal. March 29, 2016).

In addition, in 2014, the Council for Responsible Nutrition (CRN) filed a challenge with the National Advertising Division of the Better Business Bureau (NAD) regarding Obesity Research Institute’s marketing of Lipozene. Specifically, CRN argued that Obesity Research Institute’s marketing made the unsubstantiated implied claim that Lipozene may be used for disease prevention and treatment because of references to diabetes, obesity, and high cholesterol, and used testimonials that reported atypical results without clearly and conspicuously disclosing the typical results achieved from using Lipozene. Obesity Research Institute did not participate in the NAD proceeding, which prompted NAD to refer the matter to the FTC in November 2014. *See* <http://www.asrcreviews.org/nad-refers-advertising-for-obesity-research-councils-lipozene-to-ftc-for-review-after-advertiser-declines-to-participate-in-nad-proceeding/>.

⁴ Stipulated Final Judgment and Order for Permanent Injunction, Monetary and Other Equitable Relief, *FTC v. FiberThin, LLC*, No. 05-cv-1217 (S.D. Cal. June 17, 2005), ¶ I.A-C.

⁵ *Id.* at ¶ II.A-D.

⁶ *Id.* at ¶ III.

⁷ ‘Just Add Lipozene’ television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/JustAddLipozene.mp4>. *See also* Weight Loss Mountain’ television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/WeightLossMountain.mp4>.

⁸ The fine print on this screen states:

The 8 week clinical study sponsored by ORI was done under free living conditions, meaning participants were not given directions as to diet and exercise and thus were not instructed to make any changes to their daily lifestyle. Clinical data shows that the difference in the amount of weight loss experienced between the active and placebo group as 4.93 lbs, and of the 4.93 lbs of weight loss experienced by the active group, 3.86 lbs was body fat. Number 1 selling claim based on IRI sales data published on Nov. 29, 2015 and based solely on single SKU data.

<https://www.truthinadvertising.org/wp-content/uploads/2016/04/WeightLossMountain.mp4>. The study referred to in the fine print, however, appears to be the same study that existed at the time of the 2005 Order. *See infra* footnote 11.

⁹ The fine print at the bottom of the screen states:

Participants were remunerated for their time and their results were achieved in combination with diet and exercise. Results not typical. Average weight loss experienced between the active and placebo group was 4.93 lbs. Number 1 selling claim is based on ORI sales data published on May 19th 2013 and based solely on single SKU data.

<https://www.truthinadvertising.org/wp-content/uploads/2016/04/1MillionBottles.mp4>. This disclosure, however, which contains material information, is not adequately communicated to consumers.

¹⁰ <https://www.lipozene.com/reviews>; <https://www.lipozene.com/reviews?p=5>.

¹¹ Such claims may also violate Sections II.A and II.B of the Order due to the nature of the substantiation the company cites to for these claims. Specifically, Obesity Research Institute cites to three studies as support for its weight-loss claims, only two of which were published after the Order at issue. *See* <https://www.lipozene.com/clinical-studies> (citing to (1) *Effects of Glucomannan on Obese Patients: A Clinical Study*, *Internat'l J. of Obesity* (1984) 8, 289-293, available at

https://www.lipozene.com/documents/Effect_of_Glucomannan_on_Obese_Patients.pdf; (2) *Glucomannan and Obesity: A Critical Review*, *Alternative Therapies* (2005) Vol. 11, No. 6, available at https://www.lipozene.com/documents/Glucomannan_and_Obesity.pdf; (3) *Effect of glucomannan on plasma lipid and glucose concentrations, body weight, and blood pressure: systematic review and meta-analysis*, *Am. J. Clin. Nutr.* (2008), 88:1167-75, available at https://www.lipozene.com/documents/Effect_of_Glucomannan_on_Body_Weight.pdf).

However, neither of these studies meet the FTC's substantiation requirement. *See, e.g.*, FTC Staff Report, *Weight-Loss Advertising: An Analysis of Current Trends*, Sept. 2002, available at https://www.ftc.gov/sites/default/files/documents/reports/weight-loss-advertising-an-analysis-current-trends/weightloss_0.pdf. Both reports are simply reviews that summarize other studies. Furthermore, both reports clearly state that additional studies regarding the safety and efficacy of glucomannan – the active ingredient in Lipozene – are needed before it can be safely recommended. *See Glucomannan and Obesity: A Critical Review*, https://www.lipozene.com/documents/Glucomannan_and_Obesity.pdf (“[b]efore [glucomannan] can be safely recommended for widespread use, however, additional trials of standardized preparations are needed to extend extant data on its safety, efficacy, and weight-reducing mechanisms of action.”); *Effect of glucomannan on plasma lipid and glucose concentrations, body weight, and blood pressure: systematic review and meta-analysis*, https://www.lipozene.com/documents/Effect_of_Glucomannan_on_Body_Weight.pdf (“Larger individual studies following patients for longer periods of time and evaluating both safety and efficacy are warranted and needed.”).

Obesity Research Institute's reliance on these reports may also violate Section III of the Order, which prohibits the company from misrepresenting, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study. *See* Section III of the Order.

Finally, Obesity Research Institute may also be violating Section II.D of the Order, which prohibits the company from making misrepresentations about the health-related benefits of their products without competent and reliable scientific evidence to support the claims. In this regard, the company claims that Lipozene's active ingredient has been shown in studies to improve glucose control and lower cholesterol. *See* <https://www.lipozene.com/side-effects>. In making such health claims, the company appears to be relying on the same three studies discussed above.

¹² *See* '1 Million Bottles Sold' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/1MillionBottles.mp4>.

¹³ *See* 'Just Add Lipozene' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/JustAddLipozene.mp4>.

¹⁴ *See* FAQ webpage, <https://www.lipozene.com/faqs>.

¹⁵ *See, e.g.*, FAQ webpage, <https://www.lipozene.com/faqs>.

¹⁶ *See Effect of glucomannan on plasma lipid and glucose concentrations, body weight, and blood pressure: systematic review and meta-analysis*, https://www.lipozene.com/documents/Effect_of_Glucomannan_on_Body_Weight.pdf.

¹⁷ *See, e.g.*, Lipozene homepage, <https://www.lipozene.com/>; How It Works page, <https://www.lipozene.com/side-effects>.

¹⁸ *See supra* footnote 11.

¹⁹ *See, e.g.*, Lipozene Home Page, <https://www.lipozene.com/>; Lipozene FAQ webpage, <https://www.lipozene.com/faqs>.

²⁰ *See* Lipozene FAQ webpage, <https://www.lipozene.com/faqs>.

²¹ *See, e.g.*, <http://www.bbb.org/reno/business-reviews/health-and-diet-products-retail/obesity-research-institute-in-reno-nv-4001223/complaints#breakdown>; <http://www.ripoffreport.com/r/Lipozene/internet/Lipozene-bombarded-with-other-offers-then-youre-put-on-autoship-without-knowledge-autosh-1239376>.

²² Restore Online Shoppers' Confidence Act, 15 U.S.C. § 8403. ROSCA prohibits any person from charging or attempting to charge any consumer for goods or services sold on the Internet through any negative option offer, unless the person: (1) provides text that clearly and conspicuously discloses all material terms of the transaction before obtaining the consumer's billing information; (2) obtains a consumer's express informed consent before charging the consumer's account; and (3) provides simple mechanisms for a consumer to stop recurring charges.

²³ *See* '1 Million Bottles Sold' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/1MillionBottles.mp4>.

²⁴ *See, e.g.*, 'Just Add Lipozene' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/JustAddLipozene.mp4>; 'Water v.

Fat' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/WatervFat.mp4>; and Weight Loss Mountain' television commercial, available at <https://www.truthinadvertising.org/wp-content/uploads/2016/04/WeightLossMountain.mp4>.

²⁵ See Lipozene FAQ webpage, <https://www.lipozene.com/faqs>.