# IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS STATE OF MISSOURI

JEREMIAH W. (JAY) NIXON,	)	
Attorney General of the State of Missouri,	)	
	)	
Plaintiff,	)	
vs.	)	Cause No.
	)	
MUSCLETECH RESEARCH &	)	
DEVELOPMENT, INC.,	)	
	)	
Defendant.	)	

#### **PETITION**

Plaintiff, the Attorney General of the State of Missouri, Jeremiah W. (Jay) Nixon, in his official capacity, states the following:

#### **INTRODUCTION**

1. Defendant MuscleTech Research and Development, Inc. ("MuscleTech") has made and sold purported weight loss products under the name "Hydroxycut" containing ephedra alkaloids. Such products continue to be sold at least at the retail level. The product is not "clinically proven" to be a "fat-burner," as MuscleTech claims. MuscleTech's own study showed that Hydroxycut has no efficacy as compared to placebo with the possible exception of an appetite-suppressing effect. Moreover, the serious adverse health risks of Hydroxycut with ephedra – including death – were not adequately described or disclosed in marketing and labeling of the product. This conduct violated the Missouri Merchandising Practices Act.

#### **PARTIES**

- 2. Jeremiah W. (Jay) Nixon is the duly elected, qualified and acting Attorney General of the State of Missouri and brings this action in his official capacity pursuant to his common law, constitutional, and statutory authority, including but not limited to Chapters 27 and 407 of the Missouri Revised Statutes (as amended), and regulations promulgated thereunder. David Cosgrove, Erwin Switzer, and Jake Zimmerman are duly appointed, qualified and acting Assistant Attorneys General.
- 3. MuscleTech Research and Development, Inc. is and at all times relevant was a Canadian corporation, conducting business in the state of Missouri, with its principal place of business located at 7050 Telford Way, Unit 100, Mississauga, Ontario, Canada L5S 1V7.

### **JURISDICTION AND VENUE**

- 4. Section 407.100.1-3 provides:
  - 1. Whenever it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in any method, act, use, practice or solicitation or any combination thereof, declared to be unlawful by this chapter, he may seek and obtain, in an action in a circuit court, an injunction prohibiting such person from continuing such methods, acts, uses, practices or solicitations or any combination thereof, or engaging therein, or doing anything in furtherance thereof.
  - 2. In any action under subsection 1 of this section, and pursuant to the provisions of the Missouri Rules of Civil Procedure, the attorney general may seek and obtain temporary restraining orders, preliminary injunctions, temporary receivers and the sequestering of any funds or accounts if the court

<sup>&</sup>lt;sup>1</sup>Unless otherwise indicated, all statutory references are to Missouri Revised Statutes (2000), as presently amended.

finds that funds or property may be hidden or removed from this state or that such orders or injunctions are otherwise necessary.

- 3. If the court finds that the person has engaged in, is engaging in, or is about to engage in any method, act, use, practice or solicitation, or any combination thereof, declared to be unlawful by this chapter, it may make such orders or judgments as may be necessary to prevent such person from employing or continuing to employ or to prevent the recurrence of, any prohibited methods, acts, uses, practices or solicitations, or any combination thereof, declared to be unlawful by this chapter.
- 5. This Court has jurisdiction over the subject matter of this action pursuant to Chapters 27 and 407 of the Missouri Revised Statutes (as amended), and Article V of the Missouri Constitution.
- 6. This Court has personal jurisdiction over MuscleTech in the State of Missouri pursuant to Mo. Rev. Stat. § 506.500.
- 7. Venue lies in the Circuit Court of the City of St. Louis in that the violations of the Missouri Merchandising Practices Act described herein occurred, among other places, in the City of St. Louis in the State of Missouri. Mo. Rev. Stat. § 407.100.7.

#### THE MISSOURI MERCHANDISING PRACTICES ACT

8. Section 407.020 provides, in pertinent part:

The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the State of Missouri, is declared to be an unlawful practice.

\* \* \*

Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

- 9. Section 407.010(6) defines "sale" as "any sale, lease, offer for sale or lease, or attempt to sell or lease merchandise for cash or on credit."
- 10. Section 407.010(1) defines "advertisement" as "the attempt by publication, dissemination, solicitation, circulation, or any other means to induce, directly or indirectly, any person to enter into any obligation or acquire any title or interest in any merchandise."
- 11. Section 407.010(4) defines "merchandise" as any "objects, wares, goods, commodities, intangibles, real estate or services."
- 12. Section 407.010(7) defines "trade" or "commerce" as "the advertising, offering for sale, sale, or distribution, or any combination thereof, of any services and any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated. The terms 'trade' and 'commerce' include any trade or commerce directly or indirectly affecting the people of this state."

#### **DEFENDANT'S TRADE PRACTICES**

13. MuscleTech engaged in the design, manufacture, labeling, packaging, advertising, distribution and/or sale of Hydroxycut, a purported weight loss supplement. For purposes of this petition, "Hydroxycut" refers to the Hydroxycut product that includes ephedra or ephedra alkaloids.

- 14. Hydroxycut is "merchandise" as defined in the Missouri Merchandising Practices Act. Mo. Rev. Stat. § 407.010.
- 15. MuscleTech intended that Hydroxycut be sold as an over-the-counter weight loss supplement without a requirement of a physician's prescription or medical screening.
- 16. MuscleTech used deception, misrepresentation, unfair practice and/or the concealment, suppression, or omission of material fact in connection with the sale and advertisement of MuscleTech in regard to Hydroxycut's safety or lack of safety including but not limited to the following:
  - MuscleTech's web site and advertisements did not adequately disclose a. safety risks associated with Hydroxycut. Some advertisements or material supplied by MuscleTech to magazine publishers specifically stated that Hydroxycut is effective in reducing bodyfat "without any unwanted side effects," that it is "extremely safe" and that "studies" have shown the herbal equivalents to ephedrine and caffeine to be "very safe," that potential users can be "reassured" that Hydroxycut is "safe," and that even prescription drugs do not yield as much fat loss as the ingredients in Hydroxycut "with as little negative side effects." However, the results of MuscleTech's studies regarding safety did not accurately indicate the safety risks for most consumers of Hydroxycut because MuscleTech carefully screened all study subjects for health risks. This screening meant that there was no testing done on persons with physical and health characteristics of many consumers purchasing Hydroxycut over the counter (such as high blood pressure), making the results of such studies misleading for those consumers. Moreover, even after this screening was performed, MuscleTech's studies were still tainted in at least the following respects:

- i. When persons participating in several of MuscleTech's studies had to drop out because it became too dangerous for the subjects to continue or because the subjects could not tolerate Hydroxycut, the subjects were replaced by other people. In at least one study published by MuscleTech, these dropouts were concealed and not reported as an adverse effect.
- ii. One researcher at MuscleTech questioned the Manager of Research and Development of MuscleTech as to whether substituting subjects who experienced an "adverse event" was "legal." The Manager claimed that substituting subjects was acceptable clinical practice, which is not true, leading to misleading results that were touted by MuscleTech.
- iii. In at least one instance, a subject was rushed to a hospital for atrial fibrillation, which is a precursor to ventricular fibrillation (a lethal arrythmia that results in sudden cardiac death). The study of which he was a subject did not treat this event as an adverse event for purposes of its statistical analysis.
- iv. As a result of screening and drop-outs, one study began with 32 potential subjects, but only 17 completed the study. The other 15 were ignored in the results, greatly skewing the results. Further, of the 17 persons who completed the study, only 10 were using Hydroxycut, and 4 of those 10 had their dosage reduced during the study time as a result of adverse health effects.
- b. The Hydroxycut label fails to adequately warn of the risks inherent in taking the product in at least the following ways:
  - i. The label has a series of disclaimers or warnings in a type size so small it is nearly illegible and therefore useless to many consumers. A copy of the label is attached as <a href="Exhibit A">Exhibit A</a>. The attached copy is more legible than the actual label because the copy is not on a curved surface (the bottle) and because the actual label is printed on a reflective material.

- ii. A thorough reading of the disclaimers on the Hydroxycut label (which would be very difficult for most consumers) demonstrates that the disclaimers would preclude use of Hydroxycut by most of the adult population in the United States. MuscleTech, however, has no procedure for screening out the vast majority of consumers for whom MuscleTech represents the product to be inappropriate. Despite the fact that, according to the nearly illegible portion of the Hydroxycut label, very few persons could safely use Hydroxycut, MuscleTech does not state in its advertising or marketing materials that few persons can safely take Hydroxycut.
- iii. The population precluded from using Hydroxycut, according to the Hydroxycut label, includes anyone taking any prescription drug or any over-the-counter drug that includes caffeine. Also precluded is anyone taking aspirin. Also precluded is anyone taking caffeine, apparently precluding anyone who drinks coffee or cola. Also precluded without first consulting a physician are anyone with "a family history" or "any indication" of "any medical condition." Those medical conditions include, "but [are] not limited to" high blood pressure, stroke, recurrent headaches, or diabetes.
- iv. MuscleTech was aware of an alternative and far less deceptive labeling standard, publicized in a rule first proposed by the United States Food & Drug Administration in 1997, modified in 2000, and reopened on February 28, 2003. This alternative approach includes placing on the principal display panel the word "WARNING" followed by the statement: "Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids." Given the history of adverse reactions to products containing ephedra, the disclaimers on the Hydroxycut label were inadequate to inform consumers of material facts regarding the danger of the product. The alternative proposed by the FDA would have been a significant improvement and less deceptive to consumers.

- c. MuscleTech has not disclosed in any of its marketing or advertising materials that its own consultants believe there are serious concerns as to the safety of Hydroxycut. At least one person whom MuscleTech hired as an expert in litigation stated under oath that he believes people should not take products with ephedra and caffeine, such as Hydroxycut, and that he cautions people not to take these "drugs." Both he and another expert hired by MuscleTech testified separately that they would not recommend Hydroxycut to anyone.
- d. MuscleTech has not disclosed in its marketing or advertising materials that numerous adverse events, resulting from the use of products containing ephedra and/or the combination of ephedra and caffeine, have been reported to the FDA, to poison control centers, to MuscleTech itself, and to other manufacturers and retailers of ephedra products.
- e. MuscleTech states in its marketing materials that Hydroxycut "contains pharmaceutical-quality fat-loss ingredients." This statement is false and/or misleading, in that at least one person responsible for the manufacture of Hydroxycut has admitted under oath that they did not follow pharmaceutical standards for content uniformity.
- 17. MuscleTech used deception, misrepresentation, unfair practice and/or the concealment, suppression, or omission of material fact in connection with the sale and advertisement of MuscleTech in regard to Hydroxycut's efficacy, including but not limited to the following:
  - a. MuscleTech's website, advertisements, or information supplied to magazines stated that Hydroxycut was subjected to rigorous scientific tests, was a "fat-burner," and would raise the consumer's metabolic rate. The Hydroxycut label states "Lose Fat <u>Fast</u>" and "Clinically Proven." These statements are deceptive in that:

- i. At least one of MuscleTech's own studies showed that even when there was a weight loss, there was an *increase* in fat, meaning that the loss was of muscle. MuscleTech has cited this study in its advertising materials, despite a written statement by MuscleTech's president that data obtained from the study was "useless."
- ii. Another study commissioned by MuscleTech, conducted by the University of Guelph in Canada, showed that Hydroxycut does not "burn fat" and if there is any benefit, it comes from the product's anorectic (appetite-suppressing) effect.
- iii. Another study commissioned by MuscleTech showed that the subjects using a "new and improved" version of Hydroxycut showed no statistically significant weight loss that was greater than the placebo group, and even lost less weight than the placebo group. MuscleTech misrepresented the true results of this study by having one of its marketing persons submit a letter to the researcher suggesting that the researcher attribute the study's result to the horrific events of 9-11-01. The researcher complied, without explaining why the events of 9-11-01 would affect the placebo group differently.
- b. MuscleTech ran advertisements using deceptive "before" and "after" pictures. The pictures are deceptive in that, among other things:
  - i. The pictures use different lighting to convey an artificial fattening and slimming effect.
  - ii. The models in the pictures use different poses to convey an artificial fattening and slimming effect.
  - iii. The pictures and the accompanying copy do not fully disclose the extent of weight loss and muscle toning activities used by the models in conjunction with the use of Hydroxycut.

- iv. MuscleTech has used one picture (in multiple advertisements) showing a "before" photograph of a woman with a much larger abdomen than in the after picture. A copy of one such advertisement is attached as <a href="Exhibit B">Exhibit B</a>. The advertisements identify the woman as Marla Duncan and tout that she lost 35 pounds. At least some advertisements did not indicate that the "before" picture reflected post-pregnancy weight. Nor did the advertisements state that Marla Duncan has been a swimsuit and fitness model since at least 1983 (when she was 19 years old), has appeared on more than 100 magazine covers, and was Miss Fitness USA in 1990.
- 18. The conduct described above violated the Missouri Merchandising Practices

  Act.
- 19. MuscleTech acquired money from Missouri consumers as of the result of the deception, concealment, and other violations of the Missouri Merchandising Practices Act described above.
- 20. Each sale to a consumer of each bottle of Hydroxycut under the circumstances and deception and concealment described above constitutes a separate "violation" of the Missouri Merchandising Practices Act for purposes of the civil penalties provision of Mo. Rev. Stat. § 407.100.6.
- 21. Injunctive relief is necessary to prevent future violations of the Missouri Merchandising Practices Act.

#### RELIEF

WHEREFORE, Plaintiff respectfully asks this Court enter a judgment against Defendant MuscleTech Research and Development, Inc. providing at least the following forms of relief:

- A. Finding that Defendant MuscleTech Research and Development, Inc. violated the provisions of Section 407.020;
- B. Permanently enjoining, pursuant to Section 407.100, Defendant MuscleTech Research and Development, Inc. and its employees, agents, successors, assignees, and all other persons acting in concert or participation with it, from engaging in unlawful merchandising practices and from otherwise engaging in conduct that is necessary to be enjoined to prevent defendant from engaging in conduct unlawful under the Missouri Merchandising Practices Act;
- C. An Order, pursuant to Section 407.100, requiring Defendant MuscleTech Research and Development, Inc. to pay restitution in an amount to compensate any and all persons who have suffered any ascertainable loss, including, but not limited to, any moneys or property, real or personal, which Defendant MuscleTech Research and Development, Inc. may have acquired by means of any method, act, use, practice or solicitation, or any combination thereof, declared to be unlawful under Chapter 407;
- D. An Order requiring Defendant MuscleTech Research and Development, Inc. to pay, as a civil penalty, the amount of One Thousand Dollars (\$1,000.00) for each and every violation of Section 407.020, pursuant to Section 407.100.6;

- E. An Order requiring Defendant MuscleTech Research and Development, Inc. to pay to Plaintiff an amount equal to the costs of investigation and prosecution of this action, including the reasonable market value of attorney and investigator time incurred in investigation and prosecution of this action and the costs of administering the restitution fund for payments to consumers as requested above, as provided for by Section 407.130;
- F. An Order requiring Defendant MuscleTech Research and Development, Inc. to pay all court costs incurred in this cause of action, as provided for by Section 407.130;
- G. Any and all such additional and further orders as this Court deems just or otherwise appropriate.

# JEREMIAH W. (JAY) NIXON Attorney General

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