UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

JUNIOR HERMIDA, on behalf of himself and all others similarly situated,

Plaintiff,

v.

VITAMIN SHOPPE, INC.,

Defendant.
_____/

CASE NO.:

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

2:14-cv-172-FtM-38DNF

CLASS ACTION COMPLAINT

Plaintiff, Junior Hermida, by and through undersigned counsel, brings this action on his own behalf and on behalf of a Class and Subclass of persons defined herein against Defendant Vitamin Shoppe, Inc. and for his Complaint alleges, upon information and belief and based on the investigation to date of his counsel, as follows:

INTRODUCTION

1. This is a class action brought individually by Plaintiff and on behalf of a class of persons similarly situated, ("Class Members"), who purchased the dietary supplements BodyTech Whey Tech Pro 24, BodyTech 100% Casein, and BodyTech Primal Pro ("Products") from Defendant. Defendant's efficacy claims for the Products are false.

2. Sales of digestive aids and enzymes have grown over the past years reaching $136 million in the past fiscal year, up 4% from two years ago.

3. Defendant Vitamin Shoppe, Inc., advertises, manufactures, markets, sells and distributes the Products which are sold in the growing and extremely competitive fitness industry

as highly digestible protein products. Although Defendant boasts about the Products' efficacy in labeling and advertising the Products, it dramatically under-doses the digestive enzyme Aminogen® and falsely claims that lactase helps aid in the absorption and digestion of protein, such that none of the promised benefits is or can be delivered by the Products.

4. As a result of Defendant's unfair, deceptive, fraudulent, unfair and misleading practices, Plaintiff and Class Members have been unfairly deceived into purchasing the Products which they would not otherwise have purchased, or would have purchased only at a substantially lower price than that charged by Defendant.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d)(2) (diversity jurisdiction) and the Class Action Fairness Act, in that (i) there is complete diversity (Plaintiff is a citizen of Florida and Defendant is domiciled and incorporated in New Jersey and otherwise maintains its principal place of business in New Jersey, (ii) the amount in controversy exceeds $5,000,000.00 (Five Million Dollars) exclusive of interests and costs, and (iii) there are 100 or more members of the proposed Plaintiff class.

6. Defendant conducts substantial business in Florida, including the sale and distribution of the Products, and has sufficient contacts with Florida or otherwise intentionally avails itself of the laws and markets of Florida, so as to sustain this Court's jurisdiction over Defendant.

7. Venue lies in this District, pursuant to 28 U.S.C. §1391, because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this Judicial District. In addition, Defendant does business and/or transacts business in this Judicial District, and

therefore, is subject to personal jurisdiction in this Judicial District and resides here for venue purposes.

PARTIES

8. Plaintiff, Junior Hermida, is a resident and citizen of Naples, Collier County, Florida. Plaintiff purchased the BodyTech Whey Tech Pro 24 and BodyTech 100% Casein manufactured and marketed by the Defendant, on or about November 14, 2013, at a Vitamin Shoppe located in Lee County, Florida.

9. Vitamin Shoppe, Inc. is a New Jersey corporation headquartered at 2101 91st Street, North Bergen, New Jersey. Vitamin Shoppe is a retailer of nutritional products and sports supplements as well as herbs, homeopathic remedies, and beauty aids. The company currently sells its products through more than 500 stores located in 38 states and Puerto Rico, as well as through internet sales.

10. Defendant designed, tested, manufactured, marketed, advertised, warranted and/or sold the Products in Florida and throughout the United States.

11. During the Class period, Plaintiff and Class Members purchased the Products through Defendant's website www.vitaminshoppe.com and/or one of the many brick and mortar locations owned by Defendant. Plaintiff and Class Members suffered an injury in fact caused by the false, fraudulent, unfair, deceptive and misleading practices set forth in this Complaint.

FACTUAL ALLEGATIONS

12. Vitamin Shoppe is a retailer of nutritional products and sports supplements as well as herbs, homeopathic remedies, and beauty aids. The company currently sells its products through the internet and more than 500 stores located in 38 states and Puerto Rico.

13. Defendant has sold thousands of units of the Products either on its website or through its retail outlets throughout the United States.

14. Plaintiff reviewed the product's label and all of the other representations made by Defendant that are set forth herein prior to purchasing the product, BodyTech Whey Tech Pro 24 and BodyTech 100% Casein.

15. Defendant knowingly uses a common scheme of under-dosing the ingredient Aminogen® in all of the Products and falsely claiming that lactase aids in the absorption and digestion of protein.

16. Defendant's claims are false and misleading based on the omission of the material fact described below.

17. Defendant licenses the use of the ingredient Aminogen® from Triarco Industries, Inc. and had all relevant information regarding the ingredient's clinical trials made available to them.

18. Under information and belief, Defendant had access, but knowingly and/or recklessly ignored all competent and reliable scientific evidence regarding the Products' ingredient Aminogen®.

19. Defendant unapologetically, and with no remorse, boasts about the inclusion of this ingredient in the Products, but then under-doses it in the formula to make the ingredient useless.

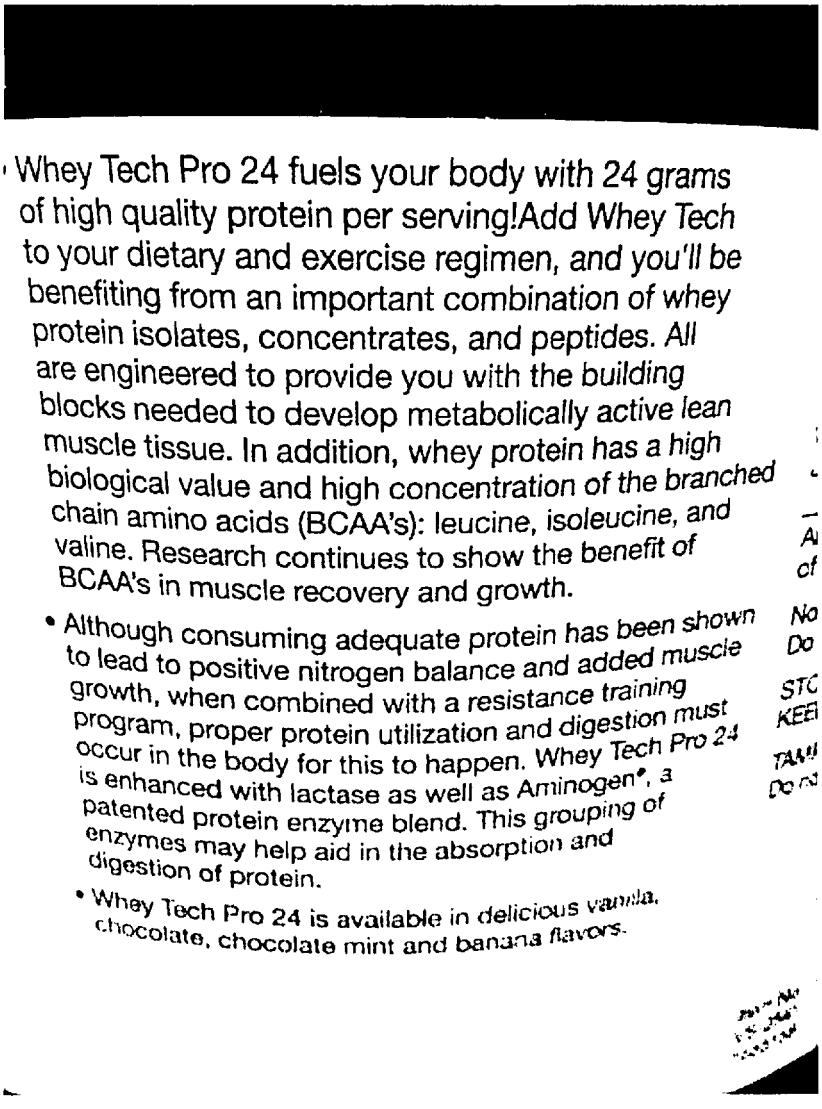
20. Under information and belief, Defendant had access, but knowingly and/or recklessly ignored all competent and reliable scientific evidence regarding the Products' ingredient lactase.

21. Defendant made false claims regarding the function of lactase in the body.

The Products' False and/or Misleading Labeling and Marketing Claims Regarding Aminogen® and Lactase

22. Defendant proudly includes the Aminogen® name and trademark symbol on the front of their Products:

23. Defendant uses the false and misleading labeling and marketing claims[1], "Whey Tech Pro 24 is enhanced with lactase as well as Aminogen®, a patented protein enzyme blend" and "This grouping of enzymes may help aid in the absorption and digestion of protein", for the Product Whey Tech Pro 24:

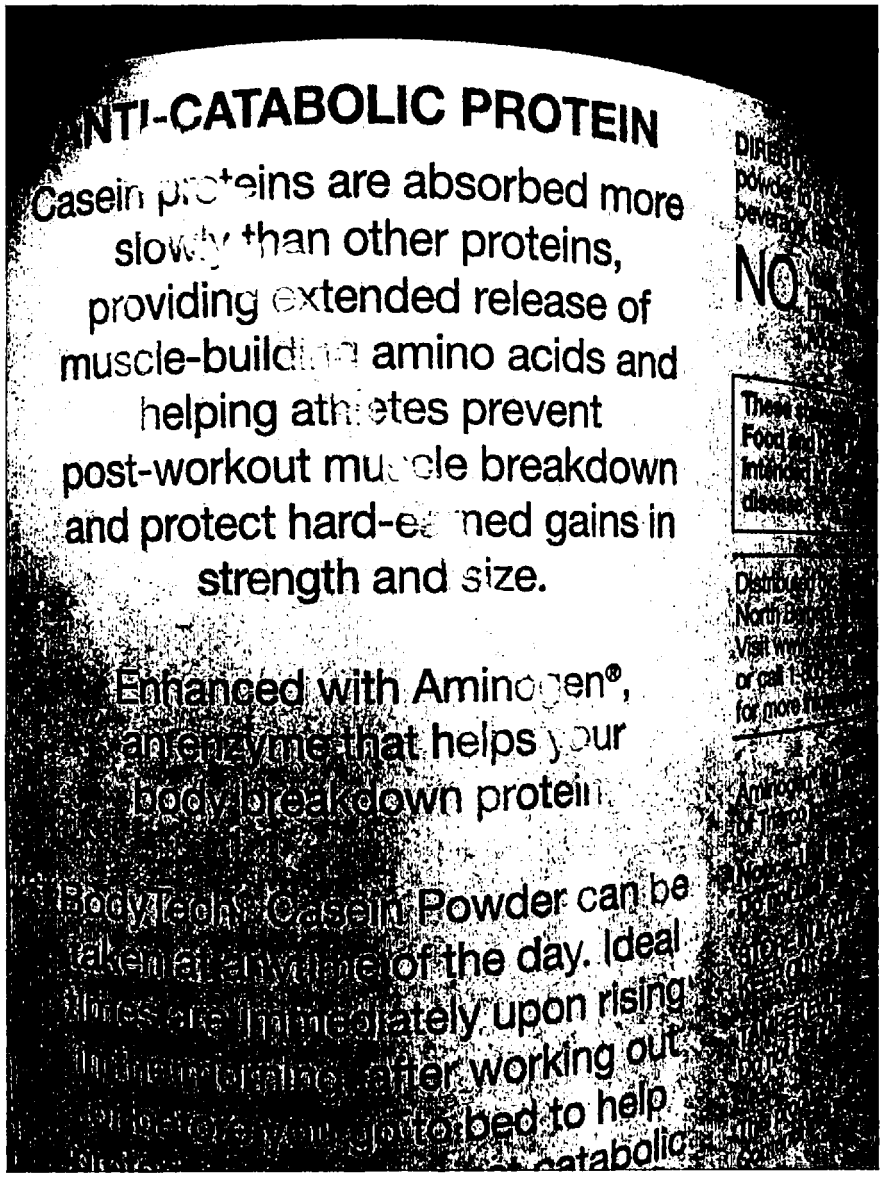


Whey Tech Pro 24 fuels your body with 24 grams of high quality protein per serving!Add Whey Tech to your dietary and exercise regimen, and you'll be benefiting from an important combination of whey protein isolates, concentrates, and peptides. All are engineered to provide you with the building blocks needed to develop metabolically active lean muscle tissue. In addition, whey protein has a high biological value and high concentration of the branched chain amino acids (BCAA's): leucine, isoleucine, and valine. Research continues to show the benefit of BCAA's in muscle recovery and growth.

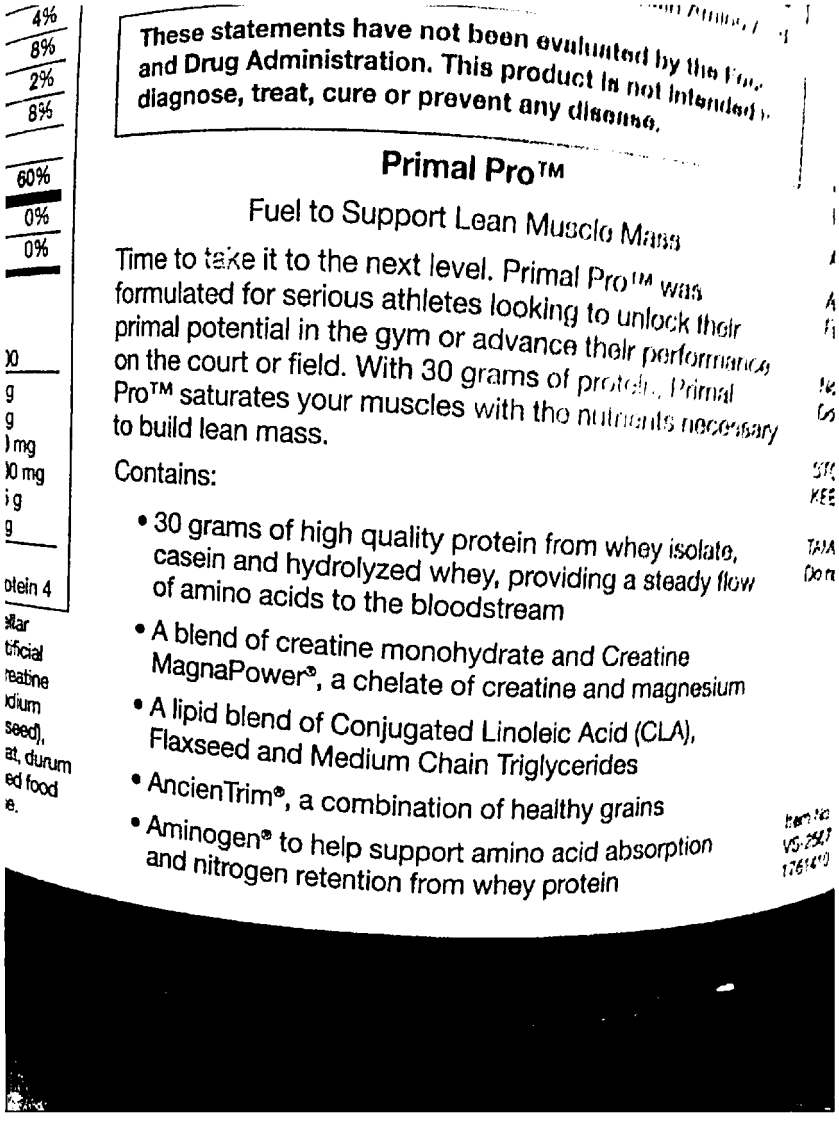
- Although consuming adequate protein has been shown to lead to positive nitrogen balance and added muscle growth, when combined with a resistance training program, proper protein utilization and digestion must occur in the body for this to happen. Whey Tech Pro 24 is enhanced with lactase as well as Aminogen®, a patented protein enzyme blend. This grouping of enzymes may help aid in the absorption and digestion of protein.
- Whey Tech Pro 24 is available in delicious vanilla, chocolate, chocolate mint and banana flavors.

[1] The description of the Products' labels is identical to the product information given by Defendant on their website.

24. Defendant uses the false and misleading labeling and marketing claim, "Enhanced with Aminogen®, an enzyme that helps your body breakdown protein" and "Enhanced with Aminogen®, an enzyme that helps your breakdown and absorb protein", for the Product 100% Casein:



25. Defendant uses the false and misleading labeling and marketing claim, "Aminogen® to help support amino acid absorption and nitrogen retention from whey protein":



Why Defendant's Labeling and Marketing Claims are False and/or Misleading Regarding Aminogen®

26. The use of the Aminogen® name and trademark on the labels of the Products is misleading to consumers because the pronouncement of the inclusion of Aminogen® clearly intends to deceive consumers into believing the Products contain effective doses of Aminogen®, which they do not.

27. Defendant's Product Whey Tech Pro 24 contains 24 grams of protein and 25 mg of Aminogen® per serving:

> Whey protein isolate, whey protein concentrate, glutamine peptides, cocoa powder, natural and artificial flavors, xanthan gum, salt, acesulfame potassium, sucralose, Aminogen and lactase. Each serving provides 25 mg of a proprietary Enzyme Blend consisting of Aminogen and lactase.
>
> http://www.vitaminshoppe.com/p/bodytech-whey-tech-pro-24-chocolate-mint-5-15-lb-powder/vs-2547?sourceType=sc&source=FG&adGroup=20-40&keyword=VS-2547&cm_mmc=Google+Shopping-_-Product+Listing+Ads-_-20-40-_-VS-2547&gclid=CIGR9MyQ6rwCFe1cMgodSS0ALA&gclsrc=aw.ds#.Uw4LMfldW7k

28. Defendant's Product 100% Casein contains 24 grams of protein, and under information and belief, 25 mg or less of Aminogen® per serving.

29. Defendant's Product Primal Pro contains 30 grams of protein, and under information and belief, 25 mg or less of Aminogen® per serving.

30. Triarco Industries, Inc. is the patent holder and licensor of Aminogen® and licenses the ingredient to Defendant.

31. Defendant relies on two studies when making their false and misleading claims regarding Aminogen®. (Exhibits A and B).

32. These two studies are the only clinical studies on Aminogen®.

33. In the first study entitled, "An open label study to determine the effects of an oral proteolytic enzyme system on whey protein concentrate metabolism in healthy males", the lowest clinical dosing used in the study was 2.5 grams of Aminogen® combined with 50 grams of whey protein concentrate. (Exhibit A).

34. In the second study entitled, "A Double-Blind Clinical Study to Investigate the

Effects of a Fungal Protease Enzyme System on Metabolic, Hepato-renal, and Cardiovascular Parameters Following 30 Days of Supplementation in Active, Healthy Men", the clinical dosing used was 3% Aminogen® in a supplementation of 40 grams of whey protein, which is approximately 1.2 grams of Aminogen® per 40 grams of whey protein. (Exhibit B).

35. Defendant's dosing of 25 mg or less of Aminogen® per serving of the Products is a fraction of the clinical dosing needed to provide the efficacy claims made by Defendant.

36. The clinically effective dosing of Aminogen® is 3-5% of the protein intake.

37. Defendant uses a dosing protocol of less than 0.1% of Aminogen® as part of the protein content in all Products.

38. At the maximum, Defendant's Products contain 1/30 of the known clinical dosage of Aminogen®.

39. At the Products' dosing protocols, and the omission of the material fact regarding the clinical doses, it is impossible for Defendant to meet their labeling and marketing claims contained herein, resulting in false and/or misleading claims regarding the Products.

Why Defendant's Labeling and Marketing Claims are False and/or Misleading Regarding Lactase

40. While the addition of lactase to the Products may certainly aid in the digestion and absorption of carbohydrates, it plays no biochemical/metabolic role for protein digestion and absorption.

41. To highlight the dichotomy of these two separate digestive systems (protein and carbohydrate), a brief explanation is below.

42. Lactase (also known as lactase-phlorizin hydrolase, or LPH), a part of the β-galactosidase family of enzymes, is a glycoside hydrolase involved in the hydrolysis of the

disaccharide lactose into constituent galactose and glucose monomers.

43. Lactase is an enzyme produced in the digestive system of humans and is present predominantly along the brush border membrane of the differentiated enterocytes lining the villi of the small intestine[2].

44. Lactase is essential to the complete digestion of whole milk. Lactase breaks down lactose, a complex sugar which gives milk its sweetness. As a large sugar compound, lactose cannot be absorbed naturally by your body. In order to metabolize this form of sugar, your body needs lactase to break down lactose into two smaller particles called glucose and galactose. These smaller sugar molecules are more easily absorbed by the cells in your intestine. Without lactase, lactose remains in your digestive tract and cannot be used by your body. Lacking lactase, a person consuming dairy products may experience the symptoms of lactose intolerance. Lactase can be purchased as a food supplement, and is added to milk to produce "lactose-free" milk products.

45. Lactase nonpersistence (or lactase insufficiency) results in incomplete digestion of an ingested load of lactose; hence lactose is malabsorbed and reaches the colon. If sufficient lactose enters the colon, the subject may experience symptoms of abdominal pain, bloating, excess flatulence, and diarrhea, a condition known as lactose intolerance[3].

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[2] Skovbjerg H, Sjöström H, Norén O (March 1981). Purification and characterisation of amphiphilic lactase/phlorizin hydrolase from human small intestine. Eur. J. Biochem. 114 (3): 653–61.

[3] Wilt TJ, Shaukat A, Shamliyan T, Taylor BC, MacDonald R, Tacklind J, Rutks I, Schwarzenberg SJ, Kane RL, and Levitt M. Lactose Intolerance and Health. No. 192 (Prepared by the Minnesota Evidence-based Practice Center under Contract No. HHSA 290-2007-10064-I.) AHRQ Publication No. 10-E004. Rockville, MD. Agency for Healthcare Research and Quality. February 2010.

46. Some people are unable to produce enough lactase to meet their metabolic needs. In some cases, the lactase enzyme is totally absent. These people are said to be suffering from lactase deficiency, or lactose intolerance[4], and lactase supplements can benefit people who suffer from lactose intolerance.

47. According to MedlinePlus, a service of the National Institutes of Health, symptoms of lactase deficiency begin 30 minutes to 2 hours after ingesting milk or a similar dairy product. Symptoms include bloating of the stomach, abdominal cramps, flatulence, nausea and diarrhea.

48. Protein digestion begins in the stomach, chiefly with the action of the hydrochloric acid that is produced there, and by **the enzyme called pepsin.**

49. Some seven or more factors influence how fast the enzymes act on the protein. These factors include the concentration of the enzyme, that is, how much of it is present; the amount of protein food needing action; the acidity of the food and of the stomach; the temperature of the food; time; and the presence of any digestion inhibitors, such as antacids. Cooking and chewing help, but protein digestion does not begin in the mouth, as carbohydrate metabolism does.

50. The hydrochloric acid in the stomach is required to break the protein bonds. The protein-containing foods are broken apart, separating out the protein, and then the proteins are broken into their constituent parts, the amino acids.

51. Protein digestion continues in the upper portion of the small intestine **under the action of the pancreatic protein enzymes, trypsin and chymotrypsin**. The amino acids are

[4] Järvelä I, Torniainen S, Kolho KL (2009). Molecular genetics of human lactase deficiencies. Ann. Med. 41 (8): 568–75.

absorbed by the blood capillaries of the small intestines, carried through the liver, and then go into the blood of the general circulation.

52. The enzyme lactase plays no role in the absorption and digestion of proteins.

RELIANCE AND INJURY

53. When purchasing the Products, Plaintiff was seeking a product that had the qualities described in Defendant's advertising, labeling and marketing.

54. Plaintiff read and relied on the deceptive claims contained therein.

55. Plaintiff believed the Products had the qualities he sought, but the Products were actually unsatisfactory to Plaintiff for the reasons described herein.

56. Plaintiff paid more for the Products, and would have been unwilling to purchase the Product at all, absent the false and misleading labeling complained of herein. Plaintiff would not have purchased the Products absent these claims and advertisements.

57. For these reasons, the Product was worth less, if it all, than what Plaintiff paid for it.

58. Instead of receiving a product that had actual and substantiated healthful or other beneficial qualities, the Product Plaintiff received was one that does not provide the claimed benefits.

59. Plaintiff lost money as a result of Defendant's deceptive claims and practices in that he did not receive what she paid for when purchasing the Product.

60. Plaintiff altered his position to his detriment and suffered damages in an amount equal to the amount he paid for the Product.

CLASS ACTION ALLEGATIONS

61. Plaintiff brings this class action on behalf of himself and all others similarly situated as Class Members pursuant to Rule 23 of the Federal Rules of Civil Procedure.

62. Plaintiff seeks to represent a "National Class" defined as follows:

All United States residents who purchased BodyTech Whey Tech Pro 24, BodyTech 100% Casein, or BodyTech Primal Pro, excluding Defendant, Defendant's officers, directors, and employees, Defendant's subsidiaries, those who purchased the products for the purpose of resale, the Judge to which this case is assigned and the immediate family of the Judge to which this case is assigned.

63. Plaintiff seeks to represent a "Florida Subclass" defined as follows:

All Florida residents who purchased BodyTech Whey Tech Pro 24, BodyTech 100% Casein, and BodyTech Primal Pro excluding Defendant, Defendant's officers, directors, and employees, Defendant's subsidiaries, those who purchased the products for the purpose of resale, the Judge to which this case is assigned and the immediate family of the Judge to which this case is assigned.

64. Plaintiff is a member of the Class that he seeks to represent. Plaintiff is a United States resident who purchased the Products.

65. Plaintiff is a member of the Class that he seeks to represent. Plaintiff is a Florida resident who purchased the Products.

66. The definition of the Class is narrowly tailored so as to include only identifiable Class Members who can be identified through Defendant's wholesale sale information. The Class has no time limit because, as discussed below, the statute of limitations has been tolled by the Defendant's fraudulent concealment of the true nature of the Product purchased by Class Members.

67. The proposed Class is so numerous that the individual joinder of all its members,

in this or any action, is impracticable. The exact number or identification of the members of the Class is presently unknown to Plaintiff, but it is believed to comprise thousands of Florida residents, and millions of United States residents, thereby making joinder impractical.

68. Common questions of fact and law exist as to all Class Members and predominate over questions affecting only individual members. These include, but are not limited to, the following:

a. Whether, in their normal and customary use by consumers, the Products work as advertised, marketed, and conveyed to consumers;

b. Whether, in the course of business, Defendant represented that the Products has characteristics, uses, benefits or qualities that it does not have when used in a customary manner by consumers;

c. Whether the claims Defendant made and is making regarding the Products are unfair or deceptive, specifically, whether the Products provide....

d. Whether Defendant knew at the time the consumer transactions took place that the consumer would not receive the promised benefits of the Products that Defendant was claiming the consumer would receive;

e. Whether Defendant knowingly made a misleading statement in connection with a consumer transaction that the consumer was likely to rely upon to his detriment;

f. Whether Defendant knew or should have known that the representations and advertisements regarding the Products were unsubstantiated, false and misleading;

g. Whether Defendant has breached express warranties in the sale and marketing of the Products;

h. Whether Defendant has been unjustly enriched by the sale of the Products to the Plaintiff and Class;

i. Whether the Plaintiff and the Class members that purchased the Products suffered monetary damages and, if so, what is the measure of those damages;

j. Whether Plaintiff and the Class members are entitled to an injunction, damages, restitution, equitable relief and other relief deemed appropriate and the amount and nature of such relief.

69. Plaintiff's claims are typical of the claims of the Class Members. Plaintiff and all Class Members purchased the Products that were designed, tested, manufactured, marketed, advertised, warranted and/or sold, and placed in the stream of commerce by Defendants. Plaintiffs and all other Class Members purchased the Products that could not perform anywhere near advertised.

70. The factual bases of Defendant's misconduct are common to the Class Members and represent a common thread of deceptive advertising and breach of warranty resulting in injury to all Class Members. Plaintiff is asserting the same rights, making the same claims, and seeking the same relief for themselves and all other Class Members. The central question of whether Defendant's representations are accurate and truthful is common to all Class members and predominates over all other questions, legal and factual in this litigation.

71. Plaintiff is an adequate representative of the proposed Class because he is a Class Member and does not have interests that conflict with those of the other Class members he seeks to represent. Plaintiff is represented by experienced and able counsel, who have litigated numerous class-action lawsuits, and Plaintiff's Counsel intend to prosecute this action vigorously for the benefit of the proposed Class. Plaintiff and their Counsel will fairly and adequately protect the interests of the Class Members.

72. A class action is the superior available method for the efficient adjudication of this litigation because:

a. The prosecution of separate actions by individual members of the Class would create a foreseeable risk of inconsistent or varying adjudications which would establish incompatible results and standards for Defendant;

b. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their own separate interests;

c. Class action treatment avoids the waste and duplication inherent in potentially thousands of individual actions, and conserves the resources of the courts; and

d. The claims of the individual class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendant, so it would be impracticable for the members of the Class to individually seek redress for Defendant's wrongful conduct. Even if the members of the Class could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

73. A class action for injunctive and equitable relief pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure is also appropriate. Defendant acted or refused to act on grounds generally applicable to the Class thereby making appropriate final injunctive and equitable relief with respect to the Class as a whole. Defendant's actions are generally applicable to the Class as a whole, and Plaintiff, on behalf of the Class, seeks damages and injunctive relief described herein. Moreover, Defendant's systemic policy and practices make declaratory relief

with respect to the Class as a whole appropriate.

FRAUDULENT CONCEALMENT

74. Defendant was and remains under a duty to Plaintiff and the Class to disclose the facts, as alleged herein. The duty to disclose the true facts arises because, as the manufacturers, Defendant is in a superior position to know the true character and quality of their products and the true facts are not something that Plaintiff and Class members could, in the exercise of reasonable diligence, have discovered independently prior to purchasing the Products.

75. The facts concealed and/or not disclosed to Plaintiff and the Class, were material facts in that a reasonable person would have considered them important in deciding whether or not to purchase the Products.

76. Defendant intentionally concealed and/or failed to disclose the shortcomings of the Products for the purpose of inducing Plaintiff and Class members to act thereon.

77. Plaintiff and Class members justifiably acted upon, or relied upon to their detriment, the concealed and/or non-disclosed material facts as evidenced by their purchase of the Products. Had they known of the true character and quality of the Products, Plaintiff and Class members would not have purchased (or would have paid less for) the Products.

78. As a direct and proximate cause of Defendant misconduct, Plaintiff and Class members have suffered actual damages. Defendant's conduct has been and is malicious, wanton and/or reckless and/or shows a reckless indifference to the interests and rights of others.

CAUSES OF ACTION

COUNT I

BREACH OF EXPRESS WARRANTY
(On Behalf of the National Class or, alternatively, the Florida Subclass)

79. Plaintiff, individually and on behalf of all others similarly situated, readopts and incorporates by reference the allegations contained in paragraphs 1 through 78 as though fully set forth herein.

80. Plaintiff and each member of the Class formed a contract with Defendant at the time they purchased the Products. The terms of the contract included the promises and affirmations of fact made by Defendant on the label of each of Defendant's Products, specifically..... Defendant's branding, labels, and advertising constitute express warranties, and are part of the basis of the bargain and a standard contract between Plaintiff, members of the Class, and Defendant.

81. Plaintiff relied on the express warranties made by defendant when he purchased the Products, including the false and misleading claims contained therein.

82. In fact, Defendant failed to disclose the material fact that the Products contained only a fraction of the clinical dose of Aminogen® and that the enzyme lactase has no role in the absorption and digestion of protein.

83. The Plaintiff and Class Members received a product that did not have an effective dose of Aminogen® when purchasing the Products.

84. The Plaintiff and Class Members received a product that contained lactase, which has no effect on protein absorption and digestion, when purchasing the Products.

85. These facts constitute breaches of all applicable express warranties as alleged in this complaint.

86. Alternatively, privity was established between Plaintiff and members of the Class and Defendant and/or its agents because Defendant was substantially if not completely responsible for directly promoting and marketing Defendant's Products to Plaintiff and the Class Member which led to Plaintiff and Class member's purchase of the Products. By virtue of this direct promotion and marketing to Plaintiff, Defendant expressly warranted the Products' attributes and benefits to members of the Class.

87. Defendant breached the terms of the express warranty by failing to provide a product that provided the benefits promised.

88. Plaintiffs relied on Defendant's affirmations of specific benefits and superior performance of alternative, less expensive, but equally effective sources of Aminogen.

89. As a result of Defendant's breaches of its express warranties, Plaintiff and the Class have been damaged in an amount to be proven at trial.

90. By reason of the foregoing, Plaintiff, on behalf of herself and all others similarly situated, demand judgment against Defendant for damages, including compensatory, incidental and consequential damages (excepting damages for personal injuries) for itself and each member of the Classes.

COUNT II

FRAUD BY UNIFORM WRITTEN MISREPRESENTATION AND OMISSION (On Behalf of the National Class or, alternatively, the Florida Subclass)

91. Plaintiff, individually and on behalf of all others similarly situated, readopts and incorporates by reference the allegations contained in paragraphs 1 through 78 as though fully set forth herein.

92. Defendant intentionally, willfully, falsely, and knowingly uniformly misrepresented material facts in writing that relate to the character and quality of the Products. Specifically, Defendant intentionally and willfully misrepresented that the Products provide certain benefits and performance characteristics in various media advertising and at point of sale materials disseminated or caused to be disseminated by Defendant.

93. Defendant also made intentional misrepresentations to Class members who sought to have Defendant honor their warranty. Defendant represented to Class members by affirmative misrepresentations and omissions that the Products provide benefits over and above what could be achieved even though it has no competent, credible, and reliable scientific evidence that is sufficient in quality and quantity, based on standards generally acceptable in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate its claims regarding the superior effectiveness of the Products.

94. Defendant's uniform written misrepresentations were made with the intent that the general public, including Plaintiff and Class, would rely upon them. Defendant's representations were made with knowledge of the falsity of such statements, or in reckless disregard of the truth thereof, and gave Defendant an unjust advantage and caused a loss to Plaintiff and Class Members. The Defendant's claims of superior effectiveness are so central to

the consumer's selection of the Products that the Defendant knew and intended that consumers would rely on those misrepresentations in determining whether to purchase the Products.

95. In actual and reasonable reliance upon Defendant's misrepresentations, Plaintiff and Class members purchased the Products for their intended and reasonably foreseeable purposes. Plaintiff and Class members were unaware of the true facts concerning the effectiveness of the Products, which were concealed from the Plaintiff and the Class Members. If Plaintiff and Class members had been aware of the concealed facts, Plaintiff and Class members would not have purchased the Products. Plaintiff's and Class members' reliance on the representations of the Defendant was reasonable.

96. Defendant misrepresented material facts with the intent to defraud Plaintiff and the Class members. Plaintiff and the Class members were unaware of the intent of Defendant and relied upon these representations in agreeing to purchase the Products.

97. In actual and reasonable reliance upon Defendant misrepresentations, Plaintiff and Class members purchased the Products and did not benefit from the Products as represented, the direct and proximate result of which was injury and harm to Plaintiff and Class members because:

a. they would not have purchased the Products if the true facts concerning its effectiveness had been known; and

b. the Products did not (and cannot) perform as promised.

COUNT III

VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT FLORIDA STATUTES §§501.201 et seq. (On Behalf of the Florida Subclass)

98. Plaintiff, individually and on behalf of all others similarly situated, readopts and incorporates by reference the allegations contained in paragraphs 1 through 78 as though fully set forth herein.

99. This is action is brought to secure redress for the unlawful, deceptive and unfair trade practices perpetrated by Defendant on behalf of Plaintiff and the Class members.

100. Plaintiff and all Class Members are "consumers" and the transactions at issue in this complaint constitute "trade or commerce" as defined by Florida Statutes § 501.203 (7) and (8) respectively.

101. Florida Statutes § 502.201, et seq. was enacted to protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive or unfair acts or practices in the conduct of any trade or commerce.

102. Defendant's actions, as alleged herein, constitute affirmative acts or representations including: unconscionable commercial practices; deception; fraud; false pretense; false promise; and/or misrepresentation, and therefore are unlawful under the FDUTPA.

103. When a FDUPTA claim is based on an affirmative act or representation, neither intent to deceive by Defendant nor actual reliance by Plaintiff or the Class need be shown.

104. Defendant's actions, as alleged herein, constitute knowing omissions and therefore are unlawful under the FDUTPA.

105. Plaintiff and the Class reasonably and justifiably relied on Defendant's deceptive, unfair, fraudulent, misrepresentations, as alleged herein. Plaintiff and members of the proposed Class and the public were certain to be deceived because Defendant knowingly failed to disclose the source, affiliation, origin, characteristics, ingredients, standards and quality of the Products. Defendant's business practices in its advertising, marketing, packaging, labeling and sales of the Products as unique and superior products justifying substantially higher prices over alternative sources of Aminogen, is an unconscionable, unfair, and deceptive act or practice in violation of the FDUPTA.

106. As a direct and proximate cause of Defendant's unlawful acts and omissions, Plaintiff and the Class have suffered an ascertainable loss of money or property, real or personal, in that they would not have purchased the Products but for Defendant's material omissions and affirmative acts or representations in connection with the marketing, advertising, and sale of the Products.

107. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, costs, and reasonable attorney's fees.

COUNT IV

UNJUST ENRICHMENT
(On Behalf of the National Class or, alternatively, the Florida Subclass)

108. Plaintiff, individually and on behalf of all others similarly situated, readopts and incorporates by reference all allegations contained in the foregoing paragraphs as though fully set forth herein.

109. Plaintiff conferred a tangible economic benefit upon Defendants by purchasing the Products. Plaintiff and members of the Class would have expected remuneration from Defendant at the time this benefit was conferred had they known that the Product did not perform as promised and has been widely criticized by government officials and scientists.

110. As a result of Defendant's deceptive, fraudulent, and misleading packaging, advertising, marketing and sales of its Products, Defendant was enriched, at the expense of the Plaintiff and each member of the Class, through the payment of the purchase price for the Products.

111. Under the circumstances, it would be against equity and good conscious to permit Defendant to retain the ill-gotten benefits that it received from Plaintiff and members of the Class in light of the fact that the Products purchased by Plaintiff and members of the Class were not as Defendant purports them to be, as set forth more fully above.

112. It would thus be unjust and inequitable for Defendant to retain the benefit without restitution or disgorgement of monies paid to Defendant for the Products, or such other appropriate equitable remedy as appropriate, to the Plaintiff and other members of the Class.

COUNT V

INJUNCTIVE RELIEF
(On Behalf of the National Class or, alternatively, the Florida Subclass)

93. Plaintiff, individually and on behalf of all others similarly situated, adopts and incorporates by reference all allegations contained in the foregoing paragraphs as though fully set forth herein.

94. Defendant has refused to act on grounds generally applicable to Plaintiff and other members of the Classes, thereby making final injunctive relief appropriate.

95. Defendant's conduct, as more fully set forth herein, both in the past and through the present day, has demonstrated a willful disregard for proven scientific facts in a clear attempt to sell a product that is no more effective than other, less expensive products.

96. Defendant persists in its deceptive and unfair marketing and sales practices concerning the Products to the detriment of consumers across the country.

97. If Defendant is allowed to continue with these practices, consumers-Plaintiffs and other members of the Classes-will be irreparably harmed in that they do not have a plain, adequate, speedy, or complete remedy at law to address all of the wrongs alleged in this Complaint, unless injunctive relief is granted to stop Defendant's improper conduct concerning its marketing and sale of the Product.

98. Plaintiff and the other members of the Class, is therefore, entitled to an injunction requiring Defendant its unfair and deceptive practices relating the marketing sale of the Products, as alleged herein, including the effects thereof.

99. Plaintiff seeks a Court Order requiring Defendant to do the following:

(a) discontinue advertising, marketing, packaging and otherwise representing its Products as being superior to conventional products;

(b) undertake an immediate public information campaign to inform the Injunctive Relief Plaintiff and the other members of the Injunctive Relief State Class, of the truth about Defendant's products and Defendant's prior practices relating thereto; and

(c) correct any erroneous impression the Injunctive Relief Plaintiff and the other members of the Injunctive Relief States Class may have derived concerning the nature, characteristics, or qualities of the Products, including without limitation, the placement of corrective advertising and providing written notice to the general public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Junior Hermida, individually and on behalf of other members of the Classes described in this Complaint, respectfully requests that:

A. the Court certifies the Classes pursuant to Fed. R. Civ. P. 23(b)(2) and (b)(3), and adjudge Plaintiff and his counsel to be an adequate representative thereof;

B. the Court enter an Order requiring Defendant to pay Plaintiff's and other members of the Classes' economic, monetary, actual damages (including multiple damages), consequential, compensatory, or statutory damages, whichever is greater; and, awarding Plaintiff and the other members of the Classes exemplary damages, to the extent permitted under the laws of each of the states implicated in this action;

C. the Court enter an Order awarding restitution and disgorgement of Defendant's revenues arising from its conducts alleged above, or any other appropriate remedy in equity, to Plaintiff and other members of the Classes;

D. the Court enter an Order awarding injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices set forth above; directing Defendant to cease its deceptive and misleading marketing campaign concerning its Products, and to disgorge all monies Defendant acquired by means of any act or practice declared by this Court to be wrongful;

E. the Court enter and Order awarding Plaintiff, individually and on behalf of the other members of the Classes, their expenses and costs of suit, including reasonable attorneys' fees and reimbursement of reasonable expenses, to the extent provided by the law;

F. the Court enter an Order awarding to Plaintiff individually and on behalf of the other members of the Classes, pre- and post-judgment interest, to the extent allowable ; and

G. for such other and further relief as may be just and proper.

JURY DEMAND

Pursuant to Federal Rules of Civil Procedure 38(b), Plaintiff, Junior Hermida, hereby demands a trial by jury of all claims in this Class Action Complaint so triable.

DATED: March 26, 2014

Respectfully submitted,

By: _____

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EXHIBIT A

Journal of the International Society of Sports Nutrition

BioMed Central

Research article

Open Access

An open label study to determine the effects of an oral proteolytic enzyme system on whey protein concentrate metabolism in healthy males

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Abstract

Background: Current research suggests that protein intake of 1.5 – 2.8 g/kg/day (3.5 times the current recommended daily allowance) is effective and safe for individuals trying to increase or maintain lean muscle mass. To achieve these levels of daily protein consumption, supplementing the diet with processed whey protein concentrate (WPC) in liquid form has become a popular choice for many people. Some products have a suggested serving size as high as 50 g of protein. However, due to possible inhibition of endogenous digestive enzymes from over-processing and rapid small intestine transit time, the average amount of liquid WPC that is absorbed may be only 15 g. The combined effect of these factors may contribute to incomplete digestion, thereby limiting the absorption rate of protein before it reaches the ceacum and is eliminated as waste. The purpose of this study was to determine if Aminogen®, a patented blend of digestive proteases from *Aspergillus niger* and *Aspergillus oryzae*, would significantly increase the in-vivo absorption rate of processed WPC over control values. It also investigated if any increase would be sufficient to significantly alter nitrogen (N2) balance and C-reactive protein (CRP) levels over control values as further evidence of increased WPC absorption rate.

Methods: Two groups of healthy male subjects were assigned a specified balanced diet before and after each of two legs of the study. Subjects served as their own controls. In the first leg each control group (CG) was dosed with 50 g of WPC following an overnight fast. Nine days later each test group (TG) was dosed following an overnight fast with 50 g of WPC containing either 2.5 g (A2.5) or 5 g (A5) of Aminogen®. Blood samples were collected during each leg at 0 hr, 0.5 hr, 1 hr, 2 hr, 3 hr, 3.5 hr and 4 hr for amino acid (AA) and CRP analyses. The following 18 AAs were quantified: alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine. Urine was collected for 24 hours from 0 hr for total N2 analysis. Results are expressed as means ± SEM. All significance and power testing on results was done at a level of alpha = 0.05. Area under the concentration time curve (AUC) was calculated using the trapezoidal rule. One-way analysis of variance (ANOVA-1) was done between CGs, between TGs and between time points. One-way repeated measures analysis of variance (ANOVA-1-RM) was done to compare CGs and

TGs. Two-way analysis of variance (ANOVA-2) was performed on total serum amino acid (TSAA) levels, urine N2 levels and CRP levels between each CG and TG.

Results: After baseline subtraction the mean AUC was significantly ($p \leq 0.05$) greater in each TG compared the corresponding CG. Comparison of the mean AUC between each TG and each CG was not significantly different. Total serum amino acid (TSAA) levels were significantly greater in each TG compared the corresponding CG. They were also significantly different between each TG but not between each CG. All individual serum amino acid (ISAA) levels in TG-A2.5 except glycine, histidine, methionine and serine were significantly higher than in CG-A2.5 at 4 hr. All ISAA levels in TG-A5 except methionine and serine were significantly higher than in CG-A5 at 4 hr. The N2 balance was significantly higher in each TG compared to the corresponding CG, but not significantly different between each CG and between each TG. Significant differences in CRP levels are reported between each TG compared to the corresponding CG, but not significantly different between each TG and between each CG.

Conclusion: A patented blend of digestive proteases (Aminogen®) increased the absorption rate of processed WPC over controls, as measured by statistically significant increases in AUC, TSAA levels, ISAA levels and N2 balance. Significant decreases in CRP levels and fluxes in AA levels are also reported.

Background

Increased protein consumption has become increasingly popular among individuals, especially athletes, trying to increase or maintain lean muscle mass. Whey protein concentrate (WPC) in liquid form has become a popular protein supplement because it has been characterized as rapidly and easily digestible. Clinical studies have reported that approximately 30 g of WP as a liquid meal produced a large but transient rise in postprandial plasma AA levels in approximately 90 minutes and returned to baseline within 5 hours. The rise in AA levels increased protein synthesis and nitrogen (N2) balance but did not inhibit whole body protein breakdown [1,2]. Recently, it has been reported that the intake of WP above 1.5 g/kg/day helped decrease body fat, increase lean body mass and maintain nitrogen (N2) balance [3]. Protein intake as high as 2.8 g/kg/day (3.5 times the current recommended daily allowance) was reported to have no adverse effects on renal function [4]. To help achieve these high levels of protein intake, some WPC products have a suggested serving size of 50 g. However, several factors could limit protein digestion and absorption at this level of consumption. Digestion may be compromised by industrial-scale WPC production techniques, such as spray-drying and pressurized microfiltration, which have been reported to inhibit the activity of digestive enzymes in-vitro due to over-processing [5]. The addition of proteolytic enzymes to WPC solutions has been reported to increase the degree of hydrolysis (DH), solubility and concomitant in-vitro digestibility (IVD) [6]. Absorption may be compromised by the rapid transit time through the small intestine to the ceacum, which has been reported to be an average of 1.5 hours for viscous liquids [7]. The maximum absorption rate of WP has been reported to be 8 to 10 g/hr [8]. Using these parameters, the maximum amount of WP that could be absorbed from a liquid is 15 g. The combined effects of over-processing and increased intake may contribute to incomplete WPC digestion. This could reduce some of the positive therapeutic effects of a high protein diet including increased lean muscle mass, increased N2 retention and positive cardiovascular effects such as reduced levels of C-reactive protein (CRP) [9-11]. Increasing the amount of WPC digested, before it reaches the ceacum, may increase the absorption rate and the desired outcome of a high protein diet.

Therefore, we hypothesize that the addition of digestive proteases would increase the absorption rate of WPC in-vivo, produce a positive N2 balance and decrease CRP levels. Changes in WPC absorption rate and CRP levels are determined by comparing levels of total amino acids (TSAA), individual amino acids (IAA) and CRP levels in the serum of a control group (CG) to serum levels in a test group (TG). Differences in N2 balance are determined by comparing the total urine N2 excreted in a CG to total urine N2 excreted in a TG.

Methods

Experimental design

Two groups of healthy, male subjects were dosed with 50 g of WPC as CGs and nine days later with 50 g of WPC containing either 2.5 g or 5 g of a patented proteolytic enzyme formula from food grade *Aspergillus niger* and *Aspergillus oryzae* as TGs (Aminogen®, Triarco Industries, Wayne, NJ). Serum levels of postprandial amino acids (AAs) were used to monitor differences in WPC absorp-

tion rate and urine levels of urea were used to determine total N2 [12].

Whey protein concentrate

The protein used in this study was dry WPC, 85% protein on a dry basis, 6% fat, 3% ash and 6% lactose (Alacen 131, NZP North America). It was recovered from cheese production, processed by membrane separation and spray-dried. Natural vanilla (0.2%) (Craftmaster) was added for flavor. No solubilizers, emulsifiers or other excipients were added. Control and test samples were supplied in pre-measured individual dose packets of 50 g each (42.5 g protein). Control WPC contained no proteolytic enzymes and the test WPC was blended with either 2.5 or 5 g of Aminogen®, (US patent # 5,387,422).

Subjects

Two groups of twenty-one healthy, lean, males ages 19–35, each with a body mass index (BMI) ranging from 20 to 24, volunteered for this study. None of the participants were following any particular protein-rich dietary regime, muscle-toning or bodybuilding program during the study. The study was approved and performed in accordance with the University of Yaounde I, Cameroon Institutional Review Board (IRB). Each participant was informed of the purpose, methods, and possible risks associated with the study, and informed consent was obtained from each participant. All but one participant completed the study and was not included in any statistical analyses.

Dietary protocol

Participants followed a specified, balanced diet of 2200 Kcal/day during a one week standardization period prior to the start of the study and for nine days between each leg of the study. An overnight fast was required before Day 1 and Day 2 of testing. Participants resumed the diet after the last blood draw on Day 1. Nutrient composition consisted of 40% carbohydrate, 25% protein and 35% fat. The precise weight and composition was established for each individual by a registered dietician at the University of Yaounde Teaching Hospital (CHU). Participants received a main meal of the day at the Laboratory of Nutrition and Nutritional Biochemistry, University of Yaounde 1, and given precise take-out portions for their other meals. Participants were advised to strictly follow their prescribed diets during the study period.

Control group

Before the study, all participants (n = 41) followed the standardized diet in the dietary protocol for one week and then reported to the Laboratory of Nutrition and Nutritional Biochemistry after an overnight fast for Day 1 of the study. On Day 1, control samples were collected after all participants ingested one 50 g, pre-measured packet of WPC (42.5 g protein) without Aminogen®. The entire contents of each individual serving packet were emptied into 0.5 L of distilled water, vigorously shaken and consumed. Blood samples were collected at 0 hr (baseline, immediately prior to ingestion) 0.5 hr, 1 hr, 2 hr, 3 hr, 3.5 hr and 4 hr to measure TSAA, IAA and CRP levels. Urine was collected over 24 hours from each participant at the start of fasting and pooled to measure total N2 excretion. N2 excretion from sweat and feces was not measured. The CGs were designated as CG-A2.5 (n = 21) and CG-A5 (n = 20).

Test groups

Following a second standardization period of nine days and an over-night fast, the participants returned to the Laboratory of Nutrition and Nutritional Biochemistry for Day 2 of the study. Each participant was randomly assigned to one of two TGs, receiving either 2.5 g Aminogen®, pre-blended in 50 g WPC (n = 21) or 5 g of Aminogen®, pre-blended in 50 g WPC (n = 20) designated as TG-A2.5 and TG-A5. The entire contents of each individual serving packet containing Aminogen® were emptied into 0.5 L of distilled water, vigorously shaken and consumed. Test data was determined from blood and urine. Blood samples were collected at 0 hr (baseline, immediately prior to ingestion) 0.5 hr, 1 hr, 2 hr, 3 hr, 3.5 hr and 4 hr to measure TSAA, IAA and CRP levels. Urine was collected over 24 hours and pooled to measure total nitrogen excretion. N2 excretion from sweat and feces was not measured. Following the study, the control data from each participant was compared to the data from the corresponding patient in either of the two test groups.

Sample collection

Whole blood samples (approximately 5 mL) were collected by a phlebotomist from either an affixed catheter or multiple venous punctures, and transferred to plain Vacutainer® tubes. Serum was prepared by centrifugation and stored in 200 μl aliquots at -20°C until needed for analyses. Prior to each blood draw at 0 hr, 2 hr and 4 hr, heart rate (HR) and blood pressure (BP) were recorded by an attending technician. Pooled urine from each patient in each CG and TG was collected and refrigerated until analyzed for nitrogen.

Analytical analyses

All serum and urine samples were submitted to the laboratory blinded to remove any analytical bias.

Amino acid (AA) analyses consisted of quantification of eighteen individual serum amino acids for each patient at each time point. Analyses were performed on a Beckman 6300 AA analyzer using ion exchange chromatography and a post column derivatazation with ninhydrin and UV detection. Quantification was done versus reference standard mixtures and control mixtures of known quanti-

ties of all eighteen AA (Sigma, St. Louis, MO). Within run variations in control values of greater than +/- 20% required reanalysis. AA levels are reported in mg/L and as percent AUC. TSAA levels were reported as the total sum of all eighteen AAs. The percent AUC was reported as the amount each AA contributed to the total. Urinary nitrogen was determined manually by the AOAC Kjeldahl digestion flask method [13]. Within run variations in control values of greater than +/- 20% required reanalysis. CRP was measured by a highly sensitive immunoturbidimetric assay (Dade Behring, Paris France) by forming an immune complex with specific antibodies. Within run variations in control values of greater than +/- 20% required reanalysis.

Statistical analyses

All significance and power testing on results was done at a level of alpha = 0.05. Within group analyses was done between each corresponding CG and TG and between group analyses was done between both CGs and between both TGs. The mean area under the concentration time curve (AUC) was calculated after baseline subtraction using the trapezoidal rule. One-way repeated measures analysis of variance (ANOVA-1-RM) was performed on mean AUC between each corresponding CG and TG. One-way analysis of variance (ANOVA-1) was performed on mean AUC between both CGs and between both TGs. Two-way analysis of variance (ANOVA-2) was performed on TSAA levels between each corresponding CG and TG. ANOVA-1 was performed on TSAA levels between 0 hr and each time point within each CG and TG and on area percents of each IAA level at 0 hr and 4 hr. ANOVA-2 was used on the urine N2 and CRP levels between each corresponding CG and TG. Results are expressed as means ± SEM. Statistics were performed using a commercially available software program (Origin® for Windows, version 8.0).

Results

Average TSAA levels and AUC

After baseline subtraction, the AUC of TG-A2.5 was 2.2 times greater than the corresponding CG-A2.5 and the AUC of TG-A5 was 3.5 times greater than the corresponding CG-A5. The mean area differences were significantly greater in each TG compared to the corresponding CG ($p = 0.04$). Mean area differences between both TGs and both CGs were not significantly different.

Analysis of TSAA kinetic profiles of all groups showed a progressive, time-dependant increase through 4 hr. ANOVA-2 comparison of means between CG-A2.5 and the corresponding TG-A2.5 showed differences between groups and all time points to be significant ($p = 0.05$). The interaction between time points and dose groups was also significant ($p = 0.05$). A statistical power of 1.0 was reached between all comparisons. Comparison of means between CG-A5 and the corresponding TG-A5 showed differences between groups and all time points to be significant ($p = 0.05$). The interaction between time points and dose groups was also significant ($p = 0.05$). A statistical power of 1.0 was reached between all comparisons. Comparison of means between both CGs showed no significant difference between groups, a significant difference between time points ($p = 0.05$) and no significant interaction between groups. Comparison of means between both TGs showed a significant difference between groups and time points ($p = 0.05$) but no significant interaction between groups.

ANOVA-1 comparison of mean TSAA levels between 0 hr and each time point showed significant ($p \leq 0.05$) increases in all TGs and CGs. In CG-A2.5, the mean 0 hr TSAA level of 1.71 mg/L increased significantly at each time point, except the 0.5 hr to a maximum level of 2.22 mg/L in 4 hr. In TG-A2.5 the mean 0 hr TSAA level of 2.01 mg/L increased significantly at each time point except the 0.5 hr to a maximum level of 4.23 mg/L in 4 hr (Figure 1). In CG-A5, the mean 0 hr TSAA level of 1.87 mg/L increased significantly at each time point, except the 0.5 hr to a maximum level of 2.28 mg/L in 4 hr. In TG-A5 the mean 0 hr TSAA level of 1.99 mg/L increased significantly at each time point except the 0.5 hr to a maximum level of 4.52 mg/L in 4 hr (Figure 2).

Individual amino acid levels

The relative percent AUC for each of the eighteen AAs analyzed in CG-A2.5 and TG-A2.5 at 0 hr and 4 hr is shown in Figure 3 and 4. The sum of the average area percent for each AA equals 100% of the AUC. ANOVA-1 statistical analysis between CG-A2.5 and TG-A2.5 at 0 hr showed arginine, aspartic acid, cysteine, methionine, phenylalanine, serine, tryptophan and valine (8 of 18) to be significantly ($p \leq 0.05$) different. No significant differences were found between alanine, glutamine, glycine, histidine, isoleucine, leucine, lysine, proline, threonine and tyrosine. At 0 hr statistically significant differences between CG-A5 and TG-A5 include arginine, aspartic acid, glycine, histidine, isoleucine, lysine, methionine, proline, serine and threonine (10 of 18). No significant differences were found between alanine, glutamine, cysteine, leucine, phenylalanine, tryptophan, tyrosine and valine. At 4 hr statistically significant differences between CG-A2.5 and TG-A2.5 include alanine, arginine, aspartic acid, cysteine, glutamine, isoleucine, leucine, lysine, phenylalanine, proline, threonine, tryptophan, tyrosine and valine (14 of 18). No significant differences were found in glycine, histidine, methionine and serine. At 4 hr statistically significant differences between CG-A5 and TG-A5 include alanine, arginine, aspartic acid, cysteine, glutamine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine,

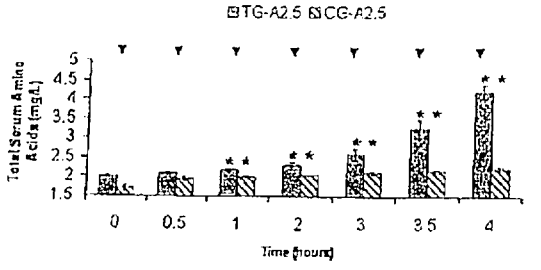

Figure 1
CG-A2.5 and TG-A2.5 Average Total Serum Amino Acids (TSAA). Average levels of TSAA in Control Group (CG) A2.5 (n = 21) and Test Group (TG) A2.5 (n = 21). Values are means ± SEM. * Indicates significant change from baseline (p = 0.05). ▼ Indicates significant difference between groups (p = 0.05).

proline, threonine, tryptophan, tyrosine and valine (16 of 18). Methionine and serine were the only two amino acids that were not significantly different.

Some AAs, including lysine, phenylalanine, tyrosine and the branched chain amino acids (BCAAs) isoleucine, leucine and valine, showed significantly greater fluctuation between 0 hr to 4 hr in each CG compared to each TG. CG-A2.5 showed a 78% decrease in the AUC of phenylalanine and a 69% decrease in tyrosine, compared to a 22% decrease and a 52% decrease, respectively, in TG-A2.5. These decreases are compensated for by a 170% increase in the AUC of lysine and a 232% increase in the AUC of BCAAs in CG-A2.5, compared to a 100% increase and a 144% increase respectively TG-A2.5.

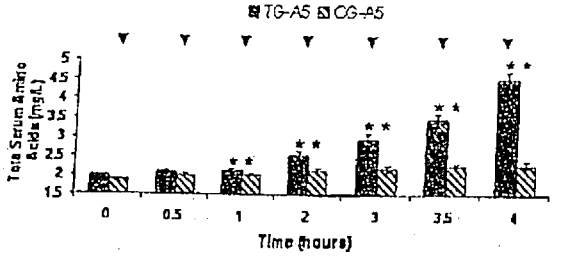

Figure 2
CG-A5 and TG-A5 Average Total Serum Amino Acids (TSAA). Average levels of TSAA in Control Group (CG) A5 (n = 21) and Test Group (TG) A5 (n = 21). Values are means ± SEM. * Indicates significant change from baseline (p = 0.05). ▼ Indicates significant difference between groups (p = 0.05).

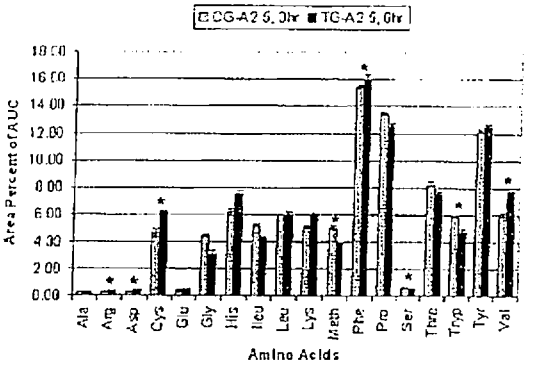

Figure 3
Individual Amino Acid AUC 0 hr. Average percent area under the curve (AUC) differences between eighteen amino acids in CG-A2.5 (n = 21) and TG-A2.5 (n = 21) at 0 hr. Values are means ± SEM. * Indicates significant difference (p = 0.05).

CG-A5 showed a 74% decrease in the AUC of phenylalanine and a 66% decrease in tyrosine between 0 hr and 4 hr, compared to an 18% decrease and a 72% decrease, respectively, in TG-A5. These decreases are compensated for by a 120% increase in the AUC of lysine and a 259% increase in the AUC of BCAAs in CG-A5 compared to an 85% increase and a 163% increase respectively TG-A5.

Nitrogen excretion

The average amount of N2 excreted in 24 hours was determined as urea for each TG and CG. ANOVA-2 showed that the mean N2 excretion decreased significantly ($p < 0.05$) in each TG compared to each corresponding CG. The mean difference between both TGs and between both CGs, as well as the interaction between both TGs and between both CGs is not significant (Figure 5). A statistical power of 1 was reached between each TG and corresponding CG. In TG-A2.5 and TG-A5 the average amount of N2 excreted over 24 hours was 7.18 g and 7.1 g respectively. In CG-A2.5 and CG-A5 the average amount of N2 excreted over 24 hours was 10.02 g and 11.05 g respectively.

C-reactive protein

CRP was measured at 0 hr, 2 hr and 4 hr in each CG and TG (Figure 6). ANOVA-2 comparison of means between each CG and corresponding TG showed significant differences ($p = 0.05$) between time points and dose groups. A statistical power of 1.0 was reached between each TG and corresponding CG. No significant differences were found when comparing the means of both CGs and both TGs. The interaction between time points was also not signifi-

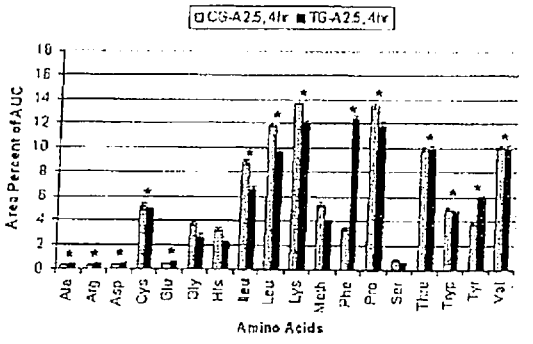

Figure 4
Individual Amino Acid AUC 4 hr. Average percent area under the curve (AUC) differences between eighteen amino acids in CG-A2.5 (n = 21) and TG-A2.5 (n = 21) at 4 hr. Values are means ± SEM. * Indicates significant difference (p = 0.05).

cant. No significant changes were found between 0 hr and 2 hr in either CG or TG. Significant ($p \leq 0.05$) reductions were found between 0 hr and 4 hr in each TG and not in either CG. TG-A2.5 showed a reduction of 10.12% and TG-A5 showed a reduction of 11.4%.

Discussion

The purpose of this study was to determine if Aminogen®, a patented blend of digestive proteases from *Aspergillus niger* and *Aspergillus oryzae*, would significantly affect the amount of processed WPC metabolized in-vivo and whether any effect would be sufficient to significantly alter N2 balance and CRP levels. Comparing levels of TSAA after ingestion, with and without Aminogen®, would indicate if the proteolytic enzymes were effective in increasing the amount of WPC metabolized.

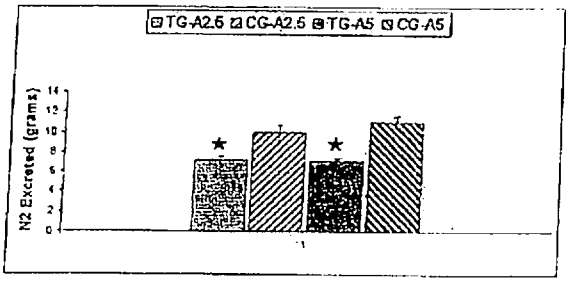

Figure 5
Total Nitrogen Excretion. Average 24 hour nitrogen excretion between Test Group (TG) A2.5 and Control Group (CG) A2.5 (n = 18). Average 24 hour nitrogen excretion between TG-A5 and CG-A5 (n = 19). Values are means ± SEM. * Indicates significant difference between corresponding TG and CG ($p = 0.05$).

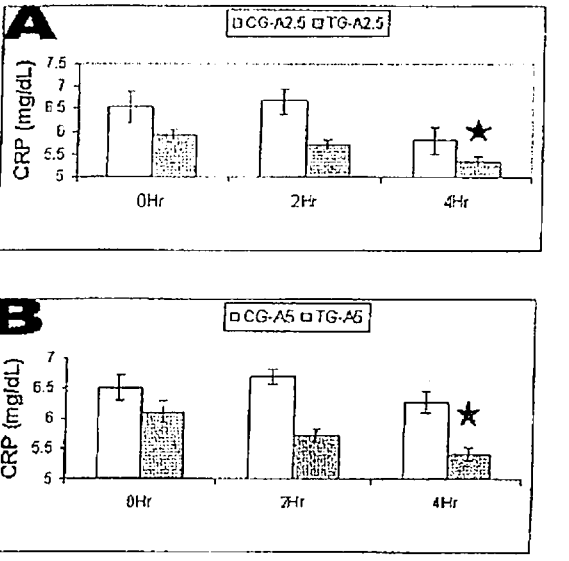

Figure 6
A. CRP Levels in Control Group (CG) and Test Group (TG) A2.5. Average C-reactive protein (CRP) levels between CG-A2.5 and TG-A2.5 (n = 16). Values are means ± SEM. * Indicates significant difference ($p = 0.05$). B. CRP Levels in Control Group (CG) and Test Group (TG) A5. Average C-reactive protein (CRP) levels between CG-A5 and TG-A5 (n = 16). Values are means ± SEM. * Indicates significant difference ($p = 0.05$).

The results show that postprandial TSAA levels were significantly increased over controls from a 50 g dose of Alacen 131 WPC containing either 2.5 or 5 g of Aminogen® (Figures 1 and 2). This indicates that protease supplementation increased the absorption rate amount of the WPC and is further supported by significant (2.2 and 3.5 times) increases in the AUC in each TG relative to each CG. After base line subtraction, no significant differences were found between the AUC of each TG indicating that the WPC absorption rate may close to maximum in TG-A2.5. Further studies may confirm this by increasing the number of TGs consuming various amounts of Aminogen®. The significantly higher levels of AAs in the TGs may be related to significant increases in N2 retention and significant decreases in CRP levels. TSAA levels in each TG appeared to be sustained much longer in this study than in earlier studies using a 30 g dose of WP isolate from milk [1,2]. Peak postprandial plasma AA levels in those studies were reported at approximately 1.5 hours and returning to baseline values in approximately five hours. In this study,

postprandial TSAA levels appear to have been still increasing or peaked at four hours. Several factors may be responsible for these differences, including the amount ingested and over-processing.

The amount of WPC ingested may have saturated endogenous proteolytic enzymes, the rate-limiting step in the digestion process. Decreased digestion from over-processing can also slow digestive enzymes [5]. These factors impede the absorption rate, which may limit the amount of protein absorbed before reaching the ceacum. The addition of Aminogen® provided more proteolytic enzymes thereby possibly increasing the absorption rate during the same time period. Whether the addition of Aminogen® affected one or more of these factors in this study is unknown at this time but the over-all effect appears to be a significant increase in the WPC absorption rate.

Results of IAA indicate that Aminogen® supplementation may contribute to decreased whole body protein metabolism. Decreased flux of IAA levels such as phenylalanine and valine have been reported to be indicators of decreased whole body protein metabolism and decreased N2 excretion [1,14]. Fluctuations in tyrosine, phenylalanine and BCAAs were compared using average percent AUC. In this model the sum of all eighteen AAs at each time point is equal to 100% of the AUC. Fluctuation in the level of one amino acid must be compensated for by an opposing relative fluctuation in one or more other amino acids. The results show significantly less fluctuation in these essential AAs between 0 hr to 4 hr in each TG than in each CG, indicating decreased whole body protein metabolism. These results, together with significant increases in TSAAs, indicate that Aminogen® supplementation may contribute to optimal conditions for protein synthesis and growth. This is consistent with a significant decrease in average N2 excretion in the TGs of 7.3 g compared to an average of 10.18 g in the CGs (equivalent to approximately 44.6 g and 63.6 g of protein, respectively). These differences offer further support that whole body protein metabolism was decreased in each TG. Further studies can verify this by subtracting baseline urinary N2 levels and measuring N2 excretion each hour during the course of the study and several hours post study. These results also suggest increased protein utilization; however blood urea nitrogen (BUN) and insulin levels should have been monitored to be more certain.

With respect to CRP levels, these results show no significant effect in each CG. However, CRP levels decreased significantly between 0 hr and 4 hr in each TG, A2.5 ($p = 0.0038$) and A5 ($p = 0.0026$). This may be related to the differences in the amount of WPC digested and absorbed between each CG and TG. Previous studies have shown that peptides produced from in-vitro, enzymatic hydrolysis of WP are bioactive in reducing CRP [11]. Supplementing with Aminogen® may contribute to significantly reducing CRP levels by producing bioactive peptides in-vivo.

Conclusion

Factors such as high protein intake and over-processing may contribute to a decreased absorption rate of WPC and lower than expected blood levels of individual amino acids. This may also cause digestion to take longer and be less complete than expected. The results of this study indicate that supplementing 50 g of WPC with 50 mg/g or 100 mg/g Aminogen®, a blend of food grade proteases from *Aspergillus niger* and *Aspergillus oryzae* patented for use as a digestive aid, significantly increased the absorption rate of WPC over controls. This is reflected in statistically significant ($p \leq 0.05$) increases in postprandial AUC, TSAA levels, ISAA levels and N2 balance. Significant decreases in CRP levels and fluxes in AA levels (possibly contributing to a decrease in whole body protein metabolism) are also reported. Further, these results indicate the need for further research in the area of enzyme supplementation for a more complete digestion of protein and perhaps other processed foods.

Competing interests

This study was funded by Triarco Industries, Inc. (Wayne, NJ) through the contract research organization (CRO) Gateway Health Alliances, Inc. All research was conducted independently and according to protocol at the Laboratory of Nutrition and Nutritional Biochemistry, University of Yaounde I, Cameroon. None of the researchers have any financial interests concerning the outcome of this investigation and the results do not constitute an endorsement by the authors and/or their institutions concerning the ingredient tested.

Authors' contributions

JO assisted in study coordination, supervision and data collection. SCK assisted in protocol development, data management and statistical analysis. MLA assisted in protocol development, clinical supply management and manuscript preparation. All authors read and approved the final manuscript.

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EXHIBIT B

Food Dig.
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A Double-Blind Clinical Study to Investigate the Effects of a Fungal Protease Enzyme System on Metabolic, Hepato-renal, and Cardiovascular Parameters Following 30 Days of Supplementation in Active, Healthy Men

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Abstract Research on the role of digestion in overall health has driven increasing interest in the use of digestive enzymes, which may improve nutrient absorption and reduce gastrointestinal symptoms. Sales of digestive aids and enzymes have grown over 8% in 2009, with enzymes accounting for $69 million of this growing category. Recent clinical research reported that acute dosing of Aminogen®, a patented blend of digestive protease enzymes isolated from *Aspergillus* and blended with whey protein concentrate, increased the rate of protein absorption. The results indicated a faster rate of amino acid absorption reflected in significantly higher blood levels of amino acids, increased nitrogen retention, and significantly reduced levels of C-reactive protein. Few studies, however, have examined the safety of repeated dosing of oral enzymes with an appropriate substrate. The purpose of this study, therefore, was to evaluate basic measures of clinical safety during 30 days of continuous, repeated dosing of Aminogen® and whey protein supplementation in healthy, active men maintaining a regimen of resistance training. Parameters evaluated include various markers of general physical health, metabolic function, hepato-renal function, and cardiovascular health including fasting blood lipids. Forty healthy, resistance-trained men (27.1±7.9 years) were recruited for this double-blind, randomized study. Group A ingested two 40-g doses of whey protein per day containing Aminogen®. Group B ingested two 40-g doses of whey protein per day. No significant changes were noted in measures of general physical health, metabolic function, cardiovascular health, and hepato-renal function within or between groups. However, total cholesterol, LDL cholesterol, and serum calcium significantly increased ($P<0.05$) in group B. In group A, whey protein containing Aminogen® was well tolerated with no adverse reactions reported. No differences in serum markers of clinical safety and an improved blood lipid profile are also reported.

Keywords Aminogen® · Fungal enzyme system · Fungal protease · Cholesterol · Safety · Aspergillus

Introduction

Research on the importance of digestion for overall health has driven increasing interest in the use of digestive enzymes, which may improve nutrient absorption and reduce gastrointestinal symptoms [1]. Sales of digestive aids and enzymes have grown over 8% in the last year, with enzymes accounting for $69 million of this growing category [2]. Although supplementing with digestive enzymes is becoming increasingly popular, there is little clinical data available regarding the safety of oral fungal proteases as digestive aids or dietary supplements. This may be due in part to confusion regarding effective dose and activity, which is substrate specific and temperature sensitive, after oral dosing. Digestive enzyme supplementation may also simply be presumed to be safe, since enzymes have been used in food processing and as food additives for almost a century. The heat generated in food processing and cooking typically destroys enzyme activity

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before ingestion [3]. Conversely, activity of enzymes for dietary supplementation should be intact to aid in digestion when taken orally. Recent clinical research has shown that Aminogen®, a patented oral fungal protease blend, maintains activity after oral dosing. Acute dosing of Aminogen® with whey protein concentrate was effective for increasing the rate of protein absorption [4]. Forty healthy males were divided into two groups and received either 50 g whey protein concentrate (80% protein) or 50 g of whey protein concentrate with Aminogen®. The results indicated a faster rate of amino acid absorption reflected in significantly higher blood levels of amino acids and increased nitrogen retention in the Aminogen® group; significant reductions in C-reactive protein levels were also reported. However, no data have been reported regarding the basic clinical safety from repeated oral dosing of the protease blend with an appropriate substrate. The purpose of this study, therefore, was to evaluate basic measures of clinical safety after combining Aminogen® and whey protein supplementation for 30 days of continuous dosing in healthy, active men maintaining a regimen of resistance training. Parameters evaluated include changes in various markers of general physical health, metabolic function, hepato-renal function, and cardiovascular health including fasting blood lipids. It is hypothesized that the addition of Aminogen® to whey protein will be well tolerated as indicated by compliance, absence of adverse events, non-significant changes in hemodynamic parameters, and normal ranges of all clinical chemistry parameters evaluated when compared to whey protein alone.

Methods

Study Design

This investigation was conducted in compliance with Good Clinical Practices, approved by an Institutional Review Board, and required the recruitment of two groups of healthy, male subjects. Following a 10-h fast, participants were assessed for resting heart rate, blood pressure weight and body mass index. Participants then donated a fasting blood sample for standard serum clinical chemistry analyses. Upon completing baseline testing, participants were assigned in a double-blind fashion to one of two treatment groups. After completing 4 weeks of a resistance training program, participants returned for a post-testing session identical to their baseline testing session. Body weight and hemodynamic and clinical chemistry data were statistically evaluated for significant differences at a significance level of 0.05. Subjects with incomplete data sets would be dropped, and no incomplete data sets were used for statistical analyses.

Subjects

A priori power analysis for this design was done based on detecting 1-kg lean mass change (delta) between groups. At a 5% level of significance, a sample size of 20 subjects per group yields an acceptable power (>0.75) for delta values of 0.75 to 1.25. Forty healthy men between the ages of 18 and 45 years were recruited and randomized into two parallel groups (A & B) of 20 subjects each and matched according to age, weight, body mass index, and exercise background. Twenty participants completed the study in group A, and 16 participants completed the study in group B. Data for the 36 participants that completed the study were used for all statistical analyses including baseline total mean data (Table 1). Inclusion criteria for all participants required them to: (1) be in good health according to health history questionnaire and routine blood chemistries; (2) have a body mass index of 20-35. (3) have been resistance training regularly (defined as completing three workouts per week on average) for at least 2 years according to completed physical activity questionnaire; (4) be willing and able to comply with the supplement and training protocol; and (5) have reviewed, signed, and dated the informed consent forms provided by the investigator to participate in the study. This subject profile was selected since Aminogen® has gained popularity in the sports nutrition industry.

Participants were excluded if they: (1) were currently participating or had participated in other research studies within the last 30 days; (2) had gained or lost more than 10 lb in the last 30 days; (3) did not verbally express comprehension of the informed consent document; (4) reported past or current use of anabolic steroids, IGF-1, growth hormone, or any other anabolic drugs within the past year, as well as patients who had taken thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, anti-coagulant, or androgenic medications; (5) reported having taken or were currently taking ergogenic levels of nutritional supplements that may affect muscle mass (e.g., creatine, HMB) or anabolic/catabolic hormone levels (androstenedione, DHEA, etc.) within 6 weeks prior to the start of the study; and (6) reported to have a known allergy to any ingredients in Aminogen® or whey protein. Finally, participants were excluded if they were receiving medical treatment including: (but not limited to) receiving prescription medications for or being diagnosed with any form of pulmonary, metabolic, psychiatric, neuromuscular, orthopedic, or cardiovascular condition which may alter their normal physiological adaptation to nutritional supplementation and resistance training.

Familiarization Session

All participants were familiarized with the study procedures and assessed for baseline height and weight after submitting

Table 1 Baseline (T0) anthropometric, body composition, biochemical parameters, and dietary analysis for the Aminogen®+whey protein (group A) and whey protein (group B) subject groups

Demographics	Total mean (n=36)	Group A (n=20)	Group B (n=16)	p value
Age (years)	27.1±7.9	27.8±8.2	26.4±7.6	0.61
Height (cm)	179±6	178±5	179±6	0.58
Weight (kg)	82.2±10.8	82.0±7.6	82.4±14.1	0.91
Body mass index (kg m^{-2})	25.7±2.6	25.8±1.9	25.5±3.4	0.78
Resting heart rate (bpm)	69.5±9.3	69.8±10.0	69.1±8.7	0.83
Systolic blood pressure (mmHg)	121.3±11.6	123.7±11.5	118.4±11.3	0.17
Diastolic blood pressure (mmHg)	75.7±8.6	78.9±7.9[a]	71.8±7.9	0.01
Biochemical parameters	Total Mean (n=36)	Group A (n=20)	Group B (n=16)	p value
Total cholesterol (mmol L^{-1})	3.9±0.9	4.1±0.8	3.7±0.9	0.10
HDL cholesterol (mmol L^{-1})	1.3±0.5	1.2±0.4	1.4±0.7	0.37
LDL cholesterol (mmol L^{-1})	2.3±0.8	2.5±0.8	2.1±0.8	0.15
Triglycerides (mmol L^{-1})	0.84±0.36	0.9±0.5	0.76±0.20	0.21
Glucose (mmol L^{-1})	4.9±0.4	5.0±0.4[a]	4.7±0.3	0.006
Potassium (U L^{-1})	4.27±0.29	4.33±0.33	4.19±0.22	0.16
Calcium (mg dL^{-1})	9.5±0.27	9.6±0.24	9.4±0.31	0.23
Alkaline phosphatase (U L^{-1})	69.0±15.0	71.3±15.8	66.3±14.0	0.33
AST (IU L^{-1})	28.9±17.8	33.1±22.1	23.6±8.1	0.11
ALT (IU L^{-1})	28.9±21.6	35.7±26.5[a]	20.3±7.7	0.03
BUN (mg dL^{-1})	17.6±4.5	17.7±4.92	17.6±3.98	0.99
Creatinine (mg dL^{-1})	1.80±4.47	2.32±5.2	1.15±0.17	0.37
BUN/creatinine	15.2±3.3	15.1±3.7	15.4±2.8	0.76
Total protein (U L^{-1})	7.1±0.39	7.1±0.42	7.0±0.36	0.73
Dietary intake	Total mean (n=36)	Group A (n=20)	Group B (n=16)	p value
Caloric intake (kcal/day)	2,662±670	2,609±581	2,729±782	0.60
Caloric intake (kcal/kg/day)	32.7±8.2	32.1±7.9	33.4±8.7	0.63
Carbohydrate (g/kg/day)	3.3±1.0	3.2±1.1	3.4±0.9	0.47
Protein (g/kg/day)	2.9±1.0	2.8±0.7	3.0±1.3	0.64
Fat (g/kg/day)	0.9±0.3	0.92±0.3	0.88±0.4	0.74

All data are presented as means±SD at baseline. Significance level was set at 0.05

a completed, signed Informed Consent Agreement. Standing height was measured by a wall-mounted stadiometer while body mass was assessed using SECA 767 Medical scale (±0.1 kg). All participants met with the study dietitian, who provided education and background on how to properly complete a 3-day food intake record based on household measures. The initial baseline testing session was scheduled no less than 4 days and typically no more than 2 weeks after completion of familiarization.

Procedures

Participants were instructed to avoid heavy exercise for the 48 h prior to their scheduled initial testing session. Participants also completed a food intake record consisting of all food and fluid intake over a 3-day period consisting of at least two weekdays and one weekend day. All baseline food intake data were entered into Nutribase IV Nutrition Software, CyberSoft, Inc. (Phoenix, AZ) and analyzed for average energy and macronutrient intake by the study dietitian. Participants were instructed to maintain consistent eating habits relative to energy and macronutrient intake throughout the study. Additional 3-day diet records were analyzed by the study dietitian at week 2 and during post-testing (week 4) to verify that eating habits remained consistent throughout the study. No assessment was made for over- or underreporting.

Upon arrival and at all testing sessions, heart rate was determined by palpation of the radial artery, and blood pressure was taken with an automated sphygmomanometer (LifeSource UA-851V). Body weight was determined using a SECA 767 Medical scale (±0.1 kg).

Prior to arriving for all testing sessions, participants were asked to observe a 10-h fast (no eating of any food or drinking of any fluid with calories). To control for any diurnal variations in blood markers, all testing sessions

were scheduled at similar times. A fasting blood sample (~15 mL) was collected from an antecubital vein into serum separation tubes (Vacutainer™ Becton Dickson) using standard phlebotomy techniques. All blood samples were centrifuged (3,000×g) for 10 min using a standard benchtop centrifuge; serum was sent to Quest Diagnostics Laboratory (Pittsburgh, PA) for lipid and metabolic automated chemistry profiles. Lipid profile included: total cholesterol, LDL cholesterol, HDL cholesterol, and total cholesterol/HDL and triglycerides. Metabolic profile included: sodium, potassium, chloride, carbon dioxide, calcium, albumin, bilirubin, globulin, albumin/globulin, alkaline phosphatase, glucose, blood urea nitrogen (BUN), creatinine, BUN/creatinine, total protein, glomerular filtration rate, kidney and liver enzymes (aspartate aminotransferase, alanine aminotransferase).

Supplementation Protocol

Single doses of either (a) whey protein concentrate, blended with 3% Aminogen® (Triarco Industries, Wayne, NJ) and 0.2% Natural Vanilla (Craftmaster) or (b) 50 g whey protein concentrate blended with 0.2% Natural Vanilla was prepackaged, stamped with either an A or a B and shipped to the facilities of Applied Health Sciences clinical research organization (Fairlawn, OH) where the study was conducted. No solubilizers, emulsifiers, or other excipients were added to the protein concentrate. The contents of the packets were blinded to the testing facility staff as well as the subjects. Subjects were matched into parallel groups according to body mass index, weight, age, and resistance experience. They were then randomly assigned to ingest either packet A or packet B twice a day for the duration of the study. One packet was taken 30 min before resistance training, and another one was taken immediately after. On non-training days, both groups ingested their respective packets at breakfast and before bed. All packets were prepared by mixing the entire contents with 8–10 oz of water. The whey protein for both groups was Avonlac 180 (Glanbia Nutritionals, Twin Falls, ID) consisting of 80% protein, less than 10% fat, less than 5% moisture, less than 5% minerals, and 5% lactose. Consumption was matched for total caloric content and ingested at the same time of day during the study. Subjects were contacted by a study dietician weekly to monitor compliance with the supplementation protocol and complete a questionnaire (by phone) to monitor changes in appetite, stomach distress, sleep habits, muscle soreness and cramping, irritability, headache, general attitude, appetite, and any other idiosyncratic responses to the supplementation and training protocol. In addition to the weekly phone calls, participant compliance was monitored by having participants return empty packets of their supplement during post-testing (week 4). Compliance to the supplementation protocol was greater than 90% for all subjects.

Resistance Training Protocol

To get an accurate representation of current physical activity habits, all participants were asked and monitored to follow a 4-day split-body resistance training program [5]. The workout, which consisted of 12 exercises, involved upper and lower body training twice per week using a 4-day split (i.e., upper body on Monday, lower body on Tuesday, upper body on Thursday, lower body on Friday), increasing gradually in intensity and volume. Lower body exercises included leg extension, leg curl, barbell or Smith-machine squat, lunge, dead lift, and calf raise. Upper body exercises included the lat pull down, seated row, triceps press down, bench press, shoulder press, and dips. For the first 2 weeks, participants completed four sets of 12 to 15 repetitions at intensities equivalent to 10- to 12-repetition maximum loads. For the final 2 weeks, participants completed four sets of six to eight repetitions at intensities equivalent to a six- to eight-repetition maximum load. Participants rested for 2 min between each set of exercise and 2 min between each exercise. Training was documented in training logs and signed off by fitness instructors and/or gym personnel at the patient's local training facility.

Statistical Analysis

All data were first tested for normality by the Shapiro–Wilk test and standardized skewness and kurtosis z scores. If normality was violated, data were log transformed. Homogenous baseline samples were determined by using an independent samples t test on all descriptive data (age, height, weight) and body mass index variables. If baseline differences were found, data were analyzed using ANCOVA statistics with that baseline variable as a covariate. Separate 2 (group)×2 (time) mixed factorial analysis of variance with repeated measures on test to determine main and interactive effects with Bonferroni corrections applied to all confidence intervals was used for all dependent variables. When interactive effects were found, simple pairwise comparisons were used to identify all differences. A significance value of 0.05 was applied for all statistical decisions. No data sets from dropouts were included in the statistical analyses.

Results

Baseline Values

Baseline values for all participants were computed and compared to ensure homogeneity of the groups. As

indicated in Table 1, no significant ($p>0.05$) baseline differences were reported in criterion variables with the exception of resting diastolic blood pressure (group A= 78.9±7.9 vs. group B=71.8±7.9 mmHg; $p<0.05$), alanine aminotransferase (ALT) (group A=35.7±26.5 vs. group B= 20.3±7.7; $p<0.05$), and fasting glucose (group A=5.0± 0.4 mmol L^{-1} vs. group B=4.7±0.3; $p<0.01$).

Dietary Intake

Absolute (kilocalories per day) and relative (kilocalories per kilogram per day) average energy intake per person changed from 2,662 kcals d^{-1} at baseline (T0) to 2,597 kcals d^{-1} at the end of the 4-week protocol (T1), $p=0.047$. This reduction was estimated to be 65 kcals d^{-1}. Average carbohydrate intake changed from 3.3±1.0 g CHO kg d^{-1} at T0 to 3.2± 0.97 g CHO kg d^{-1} at T1 ($p<0.05$). Average daily protein intake changed from 2.9±0.99 g PRO kg d^{-1} at T0 to 3.1± 1.01 g PRO kg d^{-1} at T1 ($p<0.001$). No significant ($p=0.05$) interactive effects, group (G)×time (T), were found for relative carbohydrate and protein intake. Average fat intake changed from 0.9±0.35 g fat kg d^{-1} at T0 to 0.85±0.35 g fat kg d^{-1}. A significant ($p=0.05$) interaction was found for fat intake normalized to body mass in kilograms as the relative fat intake remained constant in group B and was 11% lower in group A at T1 ($p=0.044$).

Adverse Events and Compliance

Adverse event forms were provided by the clinical research facility. Participants were required to submit adverse event reports at the conclusion of the study or upon withdrawal of the study for any reason. Some episodes of upset stomach, nausea, and headache were reported to the study dietitian from both groups but none serious enough to require dropping out of the study. No adverse event forms were submitted from supplementation was reported from either group. Compliance to the supplementation protocol was reported to be greater than 90% as indicated by returned packets and weekly follow-up by the fitness staff. Similarly, compliance to the resistance protocol was recorded by fitness staff and was reported to be greater than 90% as four participants reported missing no more than two workouts. Two subjects in group B did not finish due to injury and illness. Two others in group B were eliminated due to incomplete data sets.

Markers of Metabolic and Cardiovascular Health

No significant ($p>0.05$) main or interactive effects ($G\times T$) were reported for resting heart rate, systolic blood pressure, and diastolic blood pressure. Although an interactive effect for diastolic blood pressure began to approach significance ($G\times T$; $p=0.06$), all values for both groups A and B reported diastolic blood pressure values in normally expected ranges (Table 2). No significant ($p=0.05$) changes were reported for serum levels of HDL cholesterol, triglycerides, and glucose and the ratio of total and HDL cholesterol. A significant ($p=0.05$) interactive effect was found for serum total cholesterol values. Table 2 shows serum levels did not change for group A while a significant ($p=0.05$) increase in total cholesterol values was reported in group B (whey protein only). Similar findings were also reported for LDL cholesterol as serum changes in group A were not significant ($p=0.05$), but LDL cholesterol values in group B increased significantly ($p=0.05$).

Other Serum Clinical Markers

No significant ($p>0.05$) interactive effects were found for the following variables: sodium ($G\times T$; $p=0.87$), chloride ($G\times T$; $p=0.82$), carbon dioxide ($G\times T$; $p=0.84$), bilirubin ($G\times T$; $p=0.91$), albumin ($G\times T$; $p=0.59$), globulin ($G\times T$; $p=0.61$), albumin/globulin ($G\times T$; $p=0.70$), glomerular filtration rate ($G\times T$; $p=0.38$), alkaline phosphatase ($G\times T$; $p=0.44$), AST ($G\times T$; $p=0.23$), blood urea nitrogen ($G\times T$; $p=0.19$), and total protein ($G\times T$; $p=0.51$). Main effects for time but no significant ($p=0.05$) $G\times T$ interaction effects were found for creatinine, BUN/creatinine, and albumin. All values, however, remained within expected clinical norms. Significant ($p=0.05$) $G\times T$ interaction effects were found for serum potassium and calcium (Table 3). All effects were found to remain within expected clinical values.

Discussion

The purpose of this study was to evaluate parameters of general physical health, metabolic function, cardiovascular health, and hepato-renal function when adding a specific fungal protease enzyme system to twice daily (80 g per day total) whey protein supplementation in healthy, active participants maintaining a regimen of resistance training. A number of previous reports have suggested that in an independent fashion, supplementation with whey protein [6–9] and fungal proteases [10, 11] may confer favorable health outcomes. It was initially hypothesized that the fungal protease addition to whey protein would favorably impact cardiovascular responses without instigating any unfavorable changes in glucose and lipid panels as well as markers of kidney, liver, and general metabolic function. The primary findings from this study demonstrate that 40-g doses of whey protein, twice a day, containing 3% Aminogen® are well tolerated as none of the parameters evaluated including the clinical chemistry profiles were negatively

Table 2 Metabolic and cardiovascular health marker changes for the Aminogen®+ whey protein (group A) and whey protein (group B) subject groups

Variable	Group	T0	T1	p value		
		Week 0	Week 4	Within group	Time	G×T
Resting HR (bpm)	A	69.8±10.0	69.2±7.4	0.74	0.62	0.97
	B	69.1±8.7	68.4±10.6	0.71		
Systolic BP (mmHg)	A	124±11.5	126±10.6	0.33	0.07	0.67
	B	118±11.3	122±11.0	0.83		
Diastolic BP (mmHg)	A	78.9±7.9	77.5±8.9	0.34	0.59	0.06
	B	71.8±7.9	74.1±7.9	0.06		
Total cholesterol (mmol L^{-1})	A	4.1±0.8	4.1±1.0	0.76	0.09	<0.05
	B	3.7±0.9	4.1±0.8[ab]	<0.05		
LDL cholesterol (mmol L^{-1})	A	2.51±0.82	2.46±0.94	0.74	0.12	0.05
	B	2.10±0.81	2.53±0.94[ab]	<0.05		
HDL cholesterol (mmol $^{-1}$)	A	1.22±0.41	1.20±0.39	0.55	0.20	0.29
	B	1.39±0.69	1.20±0.37	0.29		
Total Chol/HDL	A	5.1±7.7	4.5±5.2	0.36	0.49	0.11
	B	3.0±1.0	4.4±4.2	0.22		
Triglycerides (mmol L^{-1})	A	0.90±0.45	0.95±0.46	0.49	0.35	0.91
	B	0.76±0.20	0.80±0.23	0.51		
Glucose (mmol L^{-1})	A	5.02±0.36	4.84±0.58	0.18	0.32	0.28
	B	4.70±0.28	4.70±0.40	0.95		

All data are presented as group means ± standard deviation for week 0 (T0) and week 4 (T1) of the protocol. Individual main effects for time are provided as within-group p values. Group × time interaction effects are provided as $G \times T$ p values. Between-group significance indicators represent the change from T0 to T1. Significance level was 0.05

[a]Different from baseline

[b]Different than group A

affected. This is also supported by no adverse events being reported throughout the 4-week study period.

There were surprising findings regarding significant main and interactive effects reported for total cholesterol and LDL cholesterol (Table 2). Similarly, interactive effects for diastolic blood pressure strongly approached significance (p=0.06) and are worth discussing (Table 2). Interestingly, for all of these variables, significant increases were shown to occur or were very close to being significant (diastolic blood pressure; p=0.06) for only group B, the whey protein group, while no such changes were seen in group A, the Aminogen®+whey protein group. Careful interpretation of these findings is suggested, however, due to the fact that all significant changes still resulted in values which remained within clinically accepted ranges (Table 2). This change could be partially explained by a significant increase in dietary fat, but this was not reported in either group. Consumption of fat significantly (p=0.05) decreased

Table 3 Selected clinical markers of safety for the Aminogen®+whey protein (group A) and whey protein (group B) subject groups

Variable	Group	Week 0	Week 4	p value		
				Within group	Time	G×T
Potassium (U L^{-1})	A	4.33±0.33	4.25±0.24	0.23	0.57	0.05
	B	4.19±0.22	4.34±0.30	0.15		
Calcium	A	9.6±0.24	9.5±0.22	0.62	0.07	<0.05
	B	9.4±0.31	9.6±0.25[ab]	<0.05		
Alkaline phosphatase (U L^{-1})	A	71.3±15.8	71.3±18.9	0.24	0.46	0.44
	B	66.3±14.0	64.3±17.3	0.08		
AST (U L^{-1})	A	33.1±22.1	27.2±19.0	0.08	0.08	0.23
	B	23.6±8.1	22.3±5.8	0.48		
ALT (U L^{-1})	A	35.7±26.5	32.7±25.4	0.16	0.78	0.07
	B	20.3±7.7	22.6±9.3	0.23		
BUN (mg dL^{-1})	A	17.7±4.92	19.3±5.4	0.07	0.26	0.19
	B	17.6±0.98	17.5±3.7	0.90		
Creatinine (mg dL^{-1})	A	2.32±5.2	2.28±5.2[ab]	<0.001	<0.005	0.60
	B	1.15±0.17	1.10±0.14	0.65		
BUN/creatinine	A	15.1±3.7	17.2±4.6	0.20	<0.05	0.15
	B	15.4±2.8	15.8±3.1	0.65		
Total protein (U L^{-1})	A	7.1±0.42	7.2±0.42	0.63	0.17	0.51
	B	7.0±0.36	7.1±0.36	0.13		

All data are presented as group means ± standard deviation for week 0 (T0) and week 4 (T1) of the protocol. Individual main effects for time are provided as within-group p values. Group × time interaction effects are provided as $G \times T$ p values. Between-group significance indicators represent the change from T0 to T1. Significance level was 0.05 [13]

[a]Different from baseline

[b]Different than group B

over time in group A; however, total cholesterol and LDL cholesterol levels reportedly did not change. It is noteworthy that the addition of whey protein to the diet may have increased dietary fat as well as blood levels of cholesterol and LDL, but this change was made to both experimental groups. An increase in cholesterol after supplementing with whey protein has not been indicated in healthy persons [5, 7, 12]. In fact, studies in metabolically challenged populations (e.g., overweight or hypertensive participants) have shown that whey protein supplementation may help to lower cholesterol [6, 9]. It may be speculated that the proteases in Aminogen® may interact with whey protein to produce a greater cholesterol-lowering effect than whey protein alone, possibly through the production of bioactive peptides. Oben [4] reported significant decreases in C-reactive protein in a test group after an acute consumption of 5% and 10% Aminogen® blended with whey protein. Additionally, unpublished in vitro data have shown that Aminogen® hydrolyzes whey, soy, and casein proteins to produce peptides that inhibit angiotensin-converting enzyme, a mechanistic finding which may help to explain the divergent responses to diastolic blood pressure. These results suggest the possibility that the protease enzymes in Aminogen® may be producing bioactive peptides from whey protein that are not produced by endogenous protease enzymes. These peptides may help facilitate lower blood levels of total cholesterol and LDL cholesterol than peptides produced from whey protein by endogenous proteases leading to greater cardiovascular effects. Further studies may help to explain the significance of increased blood levels of total cholesterol and LDL cholesterol as well as increased diastolic blood pressure in the whey protein only group reported in this study. A more significant finding, however, may be that, as hypothesized, whey protein containing 3% Aminogen® was well tolerated by subjects and results in no significant changes in hemodynamic parameters or markers of clinical safety for cardiovascular, calcium, liver, and kidney function when compared to whey protein alone. These findings are significant because of the lack of existing safety data on fungal enzymes when used as dietary supplements. While fungal enzymes have been used for many years in food processing and as food additives, the use of active fungal enzymes as dietary supplements is currently unregulated in many countries including the European Union member countries and Canada. This is primarily due to the lack of published clinical safety data. This study may help support the safety of repeated use of the fungal proteases in Aminogen® as a dietary supplement.

In conclusion, these results indicate that twice daily supplementation of 40 g whey protein containing 3% of the active fungal protease enzyme system Aminogen® was well tolerated during this 4-week study. The addition of Aminogen® to whey protein resulted in no adverse events and did not cause any measurable negative changes in various markers of clinical health. These, as well as previous results [4], support the safety and potential benefits of ingesting Aminogen® with an appropriate substrate such as whey protein. They also indicate further research regarding the combination of Aminogen® with protein-based foods and beverages is warranted.

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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

JUNIOR HERMIDA, on behalf of himself and all others similarly situated

(b) County of Residence of First Listed Plaintiff COLLIER
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

PARKER WAICHMAN LLP 3301 Bonita Beach Road, Suite 101 Bonita Springs, Florida 34134 T: 239.390.1000

DEFENDANTS

VITAMIN SHOPPE, INC.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty	IMMIGRATION	☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w Disabilities - Employment	☐ 540 Mandamus & Other	☐ 462 Naturalization Application		☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights	☐ 463 Habeas Corpus - Alien Detainee		☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition	☐ 465 Other Immigration Actions		

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 U.S.C 1332(d); FLA. STATS. 501.201 et al;

Brief description of cause:
Defendant's deceptive practices in connection with the marketing and sale of Body Tech products

VII. REQUESTED IN COMPLAINT:

☑ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ 5,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
03/26/2014

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $400 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

(Fmac5956) ISM

2:14-cv-172-FtM-38DNF