IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

| DEREK GUBALA, individually and behalf of all others similarly situated, | on |) | No. |
|---|----|-------------|---------------------|
| Plaintiff, | |) | |
| v. | |) | |
| CVS HEALTH CORP, | |) | JURY TRIAL DEMANDED |
| Defendant. | |))) | |

CLASS ACTION COMPLAINT

Plaintiff Derek Gubala ("Plaintiff"), through his undersigned attorneys, brings this Class Action Complaint against Defendant CVS Health Corporation ("CVS" or "Defendant"), individually and on behalf of all others similarly situated, and complains and alleges upon personal knowledge as to themselves and their own acts and experiences and, as to all other matters, upon information and belief, including investigation conducted by his attorneys:

I. NATURE OF THE ACTION

- 1. This is a consumer class action brought by Derek Gubala on behalf of himself and all others similarly situated who purchased the dietary supplement CVS Whey Protein Powder (the "Product") from Defendant.
- 2. Defendant engaged in unfair and/or deceptive business practices by misrepresenting the nature and quality of the Product on the Product label, and was unjustly enriched.

II. PARTIES

- 3. Plaintiff Derek Gubala is a citizen of Illinois who purchased the Product for approximately \$20.00 in July 2014 from a CVS retail store in Bolingbrook, Illinois.
- 4. Defendant, CVS Health Corporation, is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. Defendant CVS, directly and/or through its subsidiaries, divisions or business units, wholly owned and/or controlled, sells a wide assortment of general merchandise throughout the United States, including diet and nutrition supplements. Defendant is a citizen of the States of Delaware and Rhode Island.

III. JURISDICTION AND VENUE

- 5. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. § 1332(d), Plaintiffs' claims and the claims of the other members of the Class exceed \$5,000,000 exclusive of interest and costs, and there are numerous class members who are citizens of States other than Defendants' States of citizenship.
- 6. Diversity jurisdiction exists because Plaintiff is a citizen of Illinois and Defendant is a citizen of Delaware and Rhode Island.
- 7. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District; Defendant is a corporation with a registered agent in this District and because Defendant transacts business and/or has agents within this District.

IV. GENERAL ALLEGATIONS

8. Whey is a complete protein source, meaning it contains all the essential amino acids one needs to build protein-based compounds such as muscle tissue, skin, fingernails, hair and enzymes. It is especially rich in branded-chain amino acids – leucine, isoleucine, and valine

 which are metabolized directly within one's muscles as opposed to being processed in the liver first.

- 9. Sales of whey protein products are expected to grow 62% to reach U.S. \$7.8 billion in 2018. However, due to the high level of competition in the market and the escalating price of wholesale whey protein, sellers' profit margins are slim.
- 10. Defendant designed, manufactured, warranted, advertised and sold the Product throughout the United States, and continues to do so.
- 11. To reduce its protein manufacturing costs and enhance the nitrogen content of the Product, Defendant engages in what is commonly referred to as "protein-spiking," "nitrogen-spiking," or "amino-spiking": Defendant adds nitrogen-containing, cheap, and less beneficial free form amino acids and non-protein ingredients to the Product, including Asparagine, Hydroxyproline, and the non-amino acid compound Creatine Monohydrate.
- 12. Because nitrogen is the "tag" used in protein content calculation, the addition of such ingredients is not revealed by protein content testing. In fact, the testing method is neither a direct measure of the actual protein content in the Product, nor a measure of the type of nitrogen-containing compounds in the Product.
- 13. Once the spiking agents are removed from the formula of analysis and the "bound" amino acid count is determined, the Product's true whey protein content can be determined. When the Product's whey protein content is calculated based on the total bonded amino acids in the Product, the Product's actual whey protein content is revealed to be 21.8 grams per serving. [Exhibit A].
- 14. Protein-spiking has been condemned by the American Herbal Products Association, which recently issued a standard for manufacturers for measuring the true protein

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¹ http://www.euromonitor.com/sports-nutrition-in-the-us/report

content of their products.² In addition, General Nutrition Centers, Inc., one of the largest distributors of whey protein products in the United States, has publicly criticized protein-spiking as having the effect of misleading consumers, who are unaware of the actual protein content of the spiked products they purchase.³

- 15. Several studies show that because free-form amino acids are not absorbed as effectively as whole protein, they do not provide the same beneficial effects as whole protein.⁴
- 16. Thus, Defendant's consumers pay an inflated price for the Product, which delivers less actual protein than they reasonably expect.
 - 17. Below is a picture of Defendant's Product label.⁵

² The standard (1) defines protein as a "chain of amino acids connected by peptide bonds," and provides for the exclusion of non-protein nitrogen-containing substances for protein-content calculation and labeling purposes. www.apha.org/default.aspx?tabid=441, April 1, 2014. The National Academy of Sciences similarly defines protein as macromolecules with links of amino acids; excluded from the definition are free form amino acids and creatine.

³ www.gnclivewell.com/realprotein

⁴ [List studies] Di Pasquale MG. Amino Acids and Proteins for the Athlete: The Anabolic Edge, Second Edition. Boca Raton, FL: CRC Press; 2008:190; Katsanos C, et al. Whey protein ingestion in elderly results in greater muscle protein accrual than ingestion of its constituent essential amino acid content. Nutr. Res. Oct. 2008; 28(10):651-658; Magne H, et al. Contrarily to whey and high protein diets, dietary free leucine supplementation cannot reverse the lack of recovery of muscle mass after prolonged immobilization during ageing. J. Physiol. Apr 15, 2012; 590(Pt 8): 2035-2049; Terada T, Inui K. Peptide transporters: structure, function, regulation and application for drug delivery. Curr Drug Metab. 2004;5:85-94.

⁵ The Product is sold in different flavors and quantities. Defendant's smaller Product package contains label statements which are identical in style and size proportion.



- 18. The Product's identity, "WHEY PROTEIN POWDER," is prominently stated on the front of the label. Whey protein powder is the ingredient sought by millions of American consumers.
- 19. The Product's statement of identity is intended to lead consumers to believe that the Product contains simply whey protein. This is misleading, and draws consumers' attention away from the significant amount of free form amino acids and non-protein ingredients in the protein powder. Reasonable consumers should not be forced to look beyond the misleading representations on the front of Defendant's Product label to discover the truth about the Product: that it does not provide the whey protein and corresponding health benefits it purports to deliver. Instead, reasonable consumers should be able to trust that the representations on the front of Defendant's label are consistent with the ingredient list, and not the opposite as in the case of Defendant's Product. Below the statement of identity, the label states the Product contains "26 grams of high quality protein per serving," and "Supports lean muscle & exercise recovery."

20. The truth is, however, that Defendant's Product does not contain 26 grams of "high quality" protein per serving; rather, it is spiked with free form amino acids and non-protein ingredients and only contains 21.8 grams per serving of high quality whey protein.

- 21. A reasonable consumer, looking at Defendant's Product label, is misled because the claimed "26 grams of high quality protein per serving" is not calculated based on the protein's actual whey protein content, but rather not the nitrogen-containing free from amino acids and non-protein ingredients that Defendant has used to spike the Product.
- 22. Defendant used the above-referenced statements when it marketed, advertised and promoted the Product on its website and in its weekly advertisement, and continues to do so. Defendant's protein-spiking and labeling, marketing and advertising of the Product causes real harm to consumers who require certain levels of protein supplementation in their diets. Reasonable consumers are also deceived into paying for a product and related health benefits that the Product does not deliver.
- 23. Pursuant to 21 U.S.C. § 321(ff), Defendant's Product is a "food" regulated by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, ("FDCA") and FDCA regulations.
- 24. Defendant's false, deceptive and misleading label statements violate 21 U.S.C. § 343(a)(1) and the so-called "little FDCA" statutes adopted by many states, 6 which deem food misbranded when "its labeling is false or misleading in any particular."
- 25. FDCA regulations prohibit as misleading Defendant's use of the name "WHEY PROTEIN POWDER" to describe a product that has been adulterated with substantial amounts of free form amino acids and non-protein ingredients. 21 C.F.R. § 101.18(b). Thus, using "whey

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⁶ See, e.g., 410 ILCS 620/11.

protein" as the characterizing ingredient of a protein supplement that contains substantial amounts of spiking ingredients is misleading to consumers.

- 26. Defendant uses the term "whey protein" in a way that is interchangeable with the term "protein", so the consumer is misled that protein in the product is comprised solely of whey protein.
- 27. Defendant lists L-Leucine, L-Valine, L-Isoleucine, and L-Glutamine⁷ in their "Protein-Amino Acid Blend", as "other" admitting that free form amino acids are in fact not protein, yet including them in the calculation of the Product's protein content.
- 28. The name of the Product, and the "Supplement Facts", that show 26 grams of protein per serving is intended to deceive and mislead consumers that the Whey Protein Product is derived exclusively from the Whey Protein Concentrate, Whey Protein Isolate and Partially Hydrolyzed Whey Protein contained in the "Protein-Amino Acid Blend".
- 29. Moreover, Defendant further deceptively misleads the consumer by the protein on the actual label of the product CVS Whey Protein Powder: "26 grams of high quality protein per serving".
- 30. This misleading label claim, along with the Product's name, "CVS Whey Protein Powder" is intended to mislead and deceive reasonable consumers that the protein content of the Product was derived solely from whey protein.
- 31. Defendant's false, deceptive and misleading label statements are unlawful under State Unfair and Deceptive Acts and Practices Statutes and/or Consumer Protection Acts, which prohibit unfair, deceptive or unconscionable acts in the conduct of trade or commerce.
- 32. Defendant's false and misleading claims contained herein are in violation of 21 C.F.R. § 101.18(b), making the Product misbranded.

⁷ After scientific testing, the Product is actually shown not to contain any of these free form amino acids.

- 33. Illinois has expressly adopted the federal food labeling requirements as its own and indicated that "The Director is authorized to make the regulations promulgated under this Act conform, in so far as practicable, with those promulgated under the Federal Act." Additionally, "[a] federal regulation automatically adopted pursuant to this Act takes effect in this State on the date it becomes effective as a Federal regulation." 410 ILCS 620/21.
- 34. Further, as explained above, Defendant's claims are misleading to consumers in violation of 21 U.S.C. § 343, which states, "A food shall be deemed to be misbranded—False or misleading label [i]f its labeling is false or misleading in any particular."
- 35. The ILCS incorporates the exact language of the FDCA in 410 ILCS 620/11 by stating, "A food is misbranded- (a) If its labeling is false or misleading in any particular."
- 36. Also, the ICFA provides protection for consumers when purchasing products, including Defendant's Product, by stating, "Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact..." 815 ILCS 505/2.
- 37. The introduction of misbranded food into interstate commerce is prohibited under the FDCA and all state parallel statutes cited in this Class Action Complaint.
 - 38. Defendant intended for Plaintiff and the class members to be misled.
- 39. Defendant's misleading and deceptive practices proximately caused harm to the Plaintiff and the class.

V. CLASS ACTION ALLEGATIONS

40. Plaintiff brings this action individually and as representatives of all those similarly situated pursuant to Rule 23 F.R.C.P. on behalf of the below-defined Classes:

National Class: All persons in the United States that purchased the Product.

Consumer Fraud Multi-State Class: All persons in the States of California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington that purchased the Product.⁸

Illinois Subclass: All persons in the State of Illinois that purchased the Product.

Excluded from the Classes are Defendant and its affiliates, parents, subsidiaries, employees, officers, agents, and directors. Also excluded are any judicial officers presiding over this matter and the members of their immediate families and judicial staff.

- 41. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of their claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.
- 42. **Numerosity Federal Rule of Civil Procedure 23(a)(1).** The members of the Classes are so numerous that their individual joinder herein is impracticable. On information and belief, Class members number in the thousands to millions. The precise number of Class members and their addresses are presently unknown to Plaintiff, but may be ascertained from Defendant's books and records. Class members may be notified of the pendency of this action by mail, email, Internet postings, and/or publication.

⁸ The States in the Consumer Fraud Multi-State Class are limited to those States with similar consumer fraud laws under the facts of this case: California (Cal. Bus. & Prof. Code §17200, et seq.); Florida (Fla. Stat. §501.201, et seq.); Illinois (815 Ill. Comp. Stat. 502/1, et seq.); (Massachusetts (Mass. Gen. Laws Ch. 93A, et seq.); Michigan (Mich. Comp. Laws §445.901, et seq.); Minnesota (Minn. Stat. §325F.67, et seq.); Missouri (Mo. Rev. Stat. 010, et seq.); New Jersey (N.J. Stat. §56:8-1, et seq.); New York (N.Y. Gen. Bus. Law §349, et seq.); and Washington (Wash. Rev. Code §19.86.010, et seq.).

- 43. Commonality and Predominance Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3). Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Such common questions of law or fact include:
 - a. The true nature of the protein content in the Product;
 - b. Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Product is deceptive;
 - c. Whether Defendant's actions violate the State consumer fraud statutes invoked below;
 - d. Whether Defendant was Unjustly Enriched at the expense of the Plaintiff and Class Members; and
 - e. Whether Defendant violated an Express Warranty to Plaintiff and Class Members.
- 44. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff, on behalf of himself and the other Class members. Similar or identical statutory and common law violations, business practices, and injuries are involved. Individual questions, if any, pale by comparison, in both quality and quantity, to the numerous common questions that dominate this action.
- 45. **Typicality Federal Rule of Civil Procedure 23(a)(3).** Plaintiff's claims are typical of the claims of the other members of the Classes because, among other things, all Class members were comparably injured through Defendant's uniform misconduct described above. Further, there are no defenses available to Defendant that are unique to Plaintiff.
- 46. Adequacy of Representation Federal Rule of Civil Procedure 23(a)(4).

 Plaintiff is an adequate Class representative because his interests do not conflict with the

interests of the other Class members he seeks to represent, he has retained counsel competent and experienced in complex class action litigation, and he will prosecute this action vigorously. The Classes' interests will be fairly and adequately protected by Plaintiff and his counsel.

- Absent a representative class action, members of the Classes would continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual consumers, the resulting multiplicity of lawsuits would cause undue hardship and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated purchasers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendant. The proposed Classes thus satisfy the requirements of Fed. R. Civ. P. 23(b)(1).
- 48. **Declaratory and Injunctive Relief Federal Rule of Civil Procedure 23(b)(2).** Defendant has acted or refused to act on grounds generally applicable to Plaintiff and the other members of the Classes, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to the members of the Classes as a whole.
- 49. Superiority Federal Rule of Civil Procedure 23(b)(3). A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other members of the Classes 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 Class members to individually seek redress for Defendant's wrongful conduct. Even if Class members

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

VI. CLAIMS ALLEGED

COUNT I

Violation of State Consumer Fraud Acts (On Behalf of the Multi-State Class)

- 50. Plaintiff incorporates paragraphs 1-49 as if fully set forth herein.
- 51. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class⁹ prohibit the use of unfair or deceptive business practices in the conduct of trade or commerce.
- 52. Defendant intended that Plaintiff and each of the other members of the Consumer Fraud Multi-State Class would rely upon their deceptive conduct, and a reasonable person would in fact be misled by this deceptive conduct.
- 53. As a result of the Defendant's use or employment of unfair or deceptive acts or business practices, Plaintiff and each of the other members of the Consumer Fraud Multi-State Class have sustained damages in an amount to be proven at trial.
- 54. In addition, Defendant's conduct showed malice, motive, and the reckless disregard of the truth such that an award of punitive damages is appropriate.

⁹ California (Cal. Bus. & Prof. Code §17200, et seq.); Florida (Fla. Stat. §501.201, et seq.); Illinois (815 Ill. Comp. Stat. 502/1, et seq.); (Massachusetts (Mass. Gen. Laws Ch. 93A, et seq.); Michigan (Mich. Comp. Laws §445.901, et seq.); Minnesota (Minn. Stat. §325F.67, et seq.); Missouri (Mo. Rev. Stat. 010, et seq.); New Jersey (N.J. Stat. §56:8-1, et seq.); New York (N.Y. Gen. Bus. Law §349, et seq.); and Washington (Wash. Rev. Code §19.86.010, et seq.).

COUNT II

Violation of Illinois Consumer Fraud Act 815 ILCS 505/1 et seq.

(In the alternative to Count I and on behalf of the Illinois Subclass)

- 55. Plaintiff incorporates paragraphs 1-54 as if fully set forth herein.
- 56. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1 *et seq.* ("ICFA") prohibits the use of unfair or deceptive business practices in the conduct of trade or commerce. The ICFA is to be liberally construed to effectuate its purpose.
- 57. Defendant intended that the Plaintiff and each of the other members of the Illinois Subclass would rely upon their deceptive conduct, and a reasonable person would in fact be misled by this deceptive conduct.
- 58. As a result of the Defendant's use or employment of unfair or deceptive acts or business practices, Plaintiff Porter and each of the other members of the Illinois Subclasses have sustained damages in an amount to be proven at trial.
- 59. In addition, Defendant's conduct showed malice, motive, and the reckless disregard of the truth such that an award of punitive damages is appropriate.

COUNT III Unjust Enrichment (On Behalf of the National Class)

- 60. Plaintiff incorporates paragraphs 1-59 as if fully set forth herein.
- 61. Plaintiff and the other members of the National Class conferred benefits on Defendant by purchasing the Product.
- 62. Defendant has been unjustly enriched in retaining the revenues derived from Plaintiff and the other members of the National Class' purchase of the Products. Retention of those monies under these circumstances is unjust and inequitable because Defendant's labeling of the Product was misleading to consumers, which caused injuries to Plaintiff and the other

members of the National Class because they would have not purchased the Product if the true facts would have been known.

63. Because Defendant's retention of the non-gratuitous benefits conferred on them by Plaintiff and the other members of the National Class is unjust and inequitable, Defendant must pay restitution to Plaintiff and the other members of the National Class for their unjust enrichment, as ordered by the Court.

COUNT IV

Breach of Express Warranty (On Behalf of the National Class)

- 64. Plaintiff incorporates paragraphs 1-63 as if fully set forth herein.
- 65. Plaintiff, and each member of the National Class, formed a contract with Defendant at the time Plaintiff and the other National Class members purchased the Product. The terms of the contract includes the promises and affirmations of fact made by Defendant on the Product's packaging and through marketing and advertising, as described above. This labeling, marketing and advertising constitute express warranties and became part of the basis of bargain, and are part of the standardized contract between Plaintiff and the members of the National Class and Defendant.
- 66. Defendant purports through its advertising, labeling, marketing and packaging to create an express warranty that the Product contained "26 Grams of high quality protein per serving".
- 67. Plaintiff and the National Class performed all conditions precedent to Defendant's liability under this contract when they purchased the Product.

- 68. Defendant breached express warranties about the Product and its qualities because Defendant's statement about the Product was false and the Product does not conform to Defendant's affirmations and promises described above.
- 69. Plaintiff and each of the members of the National Class would not have purchased the Product had they known the true nature of the Product's ingredients and what the Product contained.
- 70. As a result of Defendant's breach of warranty, Plaintiff and each of the members of the National Class have been damaged in the amount of the purchase price of the Product and any consequential damages resulting from the purchases.

VII. RELIEF SOUGHT

WHEREFORE, Plaintiff and the other Class members respectfully request that the Court:

- a. Certify the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure;
- Award damages, including compensatory, exemplary, statutory, incidental, consequential, actual, and punitive damages to Plaintiff and the Class in an amount to be determined at trial;
- c. Award Plaintiff and the Class their expenses and costs of the suit, prejudgment interest, post-judgment interest, and reasonable attorneys' fees;
- d. Grant restitution to Plaintiff and the Class and require Defendant to disgorge its ill-gotten gains;
- e. Permanently enjoin Defendant from engaging in the unlawful conduct set forth herein;

- f. Grant any and all such other relief as the Court deems appropriate.
- g. Grant any and all such equitable relief as the Court deems appropriate.
- h. Grant any and all damages available under the unfair and deceptive trade practices and consumer protection laws.

VIII. JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: November 11, 2014 Respectfully submitted,

/s/ Joseph J. Siprut Joseph J. Siprut jsiprut@siprut.com Gregory W. Jones gjones@siprut.com

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Counsel for Plaintiff

And the Proposed Putative Classes

* Pro Hac Vice Application Forthcoming

EXHIBIT A

Case: 1:14-cv-09039 Document #: 1-1 Filed: 11/11/14 Page 2 of 19 PageID #:19



10005 Muirlands Blvd., Suite G | Irvine, CA 92618 Phone: (949) 419-0288 | Fax: (949) 419-0294 www.chromadex.com

Process Report

Barbat, Mansour & Suciu

Customer:

PLLC

Report Number:

CDXA-PR-169-00

Address (City, State):

Detroit, MI

Project Number:

ORD68442

Purchase Order:

N/A

Date Received:

22 Sep 14

Date of Report:

24-Oct-14

Test Location:

Boulder, CO

Assay:

Analysis of CVS Whey Protein Powder Sample from Barbat, Mansour &

Suciu PLLC

PRJ-CONSOL-RPT; CDA-00100666-ATR; CDA-00100140-ARS; CDA-

Part Number:

00100156-ATR

Prepared By:

Sylesh Venkataraman, Ph.D.

24-Oct-14 Date

Sr. Director, Laboratory

Reviewed By:

Aron Erickson

24-Oct-14

24-Oct-14

Director, Laboratory Operations

Date

Approved By:

Digitally signed by Sarah Garthe Sarah Garthe DN: cn=Sarah Garthe, o=ChromaDex Analytics, ou=Quality Assurance,

email=SarahG@chromadex.com, c=US Date: 2014.10.24 15:22:57 -06'00'

Date

Quality Assurance

Signed original on file at CDXA

CDXA-PR-169-00

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SUMMARY

ABSTRACT

The Sample was received from Barbat, Mansour & Suciu PLLC for a multitude of analyses.

1) CVS Whey Protein Powder (Lot# 898224; ChromaDex sample# CDXA-14-5820)

INTRODUCTION

The sample from Barbat, Mansour & Suciu PLLC was analyzed for Free and Total amino acid content and Taurine content.

DISCUSSION

A summary of the results are included below in Table 1. Table 2 lists the individual amino acids from the total and free amino acids analyses.

Table 1; CDXA-14-5820

| Analysis | CDXA-14-5820 (mg/serving 39g) |
|-------------------------|----------------------------------|
| Total Amino acids | 21808 |
| Total Free Amino acids | 1084 |
| Total Bound Amino acids | 21808 |
| Creatine | 3060; 2250 |

CDXA-PR-169-00

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Table 2 - CDXA-14-5820

| Analyte | Units | Total Amino Acids | Free Amino Acids | Bound Amino acids |
|--------------------|------------|----------------------|---------------------|-------------------|
| Aspartic acid | mg/serving | 2320 | ND | 2320 |
| Glutamic acid | mg/serving | 3710 | ND | 3710 |
| Serine | mg/serving | 1080 | ND | 1080 |
| Histidine | mg/serving | 368 | ND | 368 |
| Glycine | mg/serving | 410 | ND | 410 |
| Threonine | mg/serving | 1540 | ND | 1540 |
| Arginine | mg/serving | 597 | ND | 597 |
| Alanine | mg/serving | 1100 | ND | 1100 |
| Tyrosine | mg/serving | 647 | ND | 647 |
| Cystine | mg/serving | 476 | ND | 476 |
| Valine | mg/serving | 1310 | ND | 1310 |
| Methionine | mg/serving | 460 | ND | 460 |
| Phenylalanine | mg/serving | 710 | ND | 710 |
| Isoleucine | mg/serving | 1440 | ND | 1440 |
| Leucine | mg/serving | 2380 | ND | 2380 |
| Lysine | mg/serving | 1950 | ND | 1950 |
| Proline | mg/serving | 1310 | ND | 1310 |
| Asparagine | mg/serving | | 790 | |
| Glutamine | mg/serving | | ND | |
| Tryptophan | mg/serving | | ND | |
| Hydroxyproline | mg/serving | | 294 | |
| Total | mg/serving | 21808 | 1084 | 21808 |
| Serving Size = 39g | | | | |

REFERENCES

- 1) CDXA-ATR-6680-00; Amino acids Base Panel of 21
- 2) CDXA-ATR-6687-00; Creatine by HPLC
- 3) Sub12; Report# 1088231-0 Total Amino acids by Profile by HPLC

REVISION HISTORY

Revision Number

Document/Changes

00

New report

Case: 1:14-cv-09039 Document #: 1-1 Filed: 11/11/14 Page 5 of 19 PageID #:22



10005 Muirlands Blvd., Suite G | Irvine, CA 92618 Phone: (949) 419-0288 | Fax: (949) 419-0294 www.chromadex.com

Analytical Test Report

Customer:

Barbat, Mansour & Suciu PLLC

Report Number:

CDXA-ATR-6680-00

Address (City, State):

Detroit, MI

Project Number:

ORD68442

Purchase Order:

Not Provided

Date Received:

22-Sep-14

Date of Report:

08-Oct-14

Test Location:

Boulder, CO

Assay:

Amino Acids Base Panel of 21 by HPLC

Part Number:

CDA-00100666-ATR

Prepared By:

Devon Cruz

08-Oct-14

Chemist

Date

Reviewed By:

Hadi Cassier

Analyst II

08-Oct-14

Date

Approved By:

Kristie Kokeny

08-Oct-14

Quality Assurance

Date

Signed original on file at CDXA

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SUMMARY

SAMPLE(S)

CVS Whey Protein Powder

Lot # 898224

CDXA # CDXA-14-5820

RESULTS

Table 1 - CDXA-14-5820

| Analyte | Units | Spec | Result | Reporting Limit |
|----------------|------------|------|--------|-----------------|
| Aspartic acid | mg/serving | | ND | 190 |
| Glutamic acid | mg/serving | | ND | 210 |
| Serine | mg/serving | | ND | 150 |
| Histidine | mg/serving | | ND | 220 |
| Glycine | mg/serving | | ND | 110 |
| Threonine | mg/serving | | ND | 170 |
| Arginine | mg/serving | | ND | 250 |
| Alanine | mg/serving | | ND | 130 |
| Tyrosine | mg/serving | | ND | 260 |
| Cystine | mg/serving | | ND | 340 |
| Valine | mg/serving | | ND | 170 |
| Methionine | mg/serving | | ND | 210 |
| Phenylalanine | mg/serving | | ND - | 230 |
| Isoleucine | mg/serving | | ND | 190 |
| Leucine | mg/serving | | ND | 190 |
| Lysine | mg/serving | | ND | 210 |
| Proline | mg/serving | | ND | 300 |
| Asparagine | mg/serving | | 790 | |
| Glutamine | mg/serving | | ND | 56 |
| Tryptophan | mg/serving | | ND | 55 |
| Hydroxyproline | mg/serving | | 294 | |

Serving Size = 39 g

ND - Not detected above reporting Limit

BRL - Below reporting limit (compound detected below RL)

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ANALYTICAL METHOD

STANDARD(S) All standards supplied by ChromaDex, unless otherwise specified.

Part/Lot

Ready to Inject Amino Acid Mix Norvaline Hydroxyproline Asparagine Glutamine Tryptophan Agilent-5061-3330 Agilent-BCBL0180V Agilent-BCBK363V ASB-00011043 Agilent-BCBK3328V Agilent-BCBB7661

LABORATORY SUPPLIES

Analytical Balance
Ultrasonication Bath
Assorted and Volumetric glassware
Syringes and Syringe Filters
HPLC glass vials and caps

SOLVENTS AND REAGENTS

Milli-Q Water
Methanol (MeOH)
Sodium Phosphate, dibasic (Na₂HPO₄)
2 N KOH
Acetonitrile (ACN)
Hydrochloric acid (HCI)
OPA (o-phthalaldehyde) – Derivatization reagent for primary amino acids
FMOC (9-fluorenyl-methyl chloroformate) – Derivatization reagent for secondary amino acids
Borate buffer (0.4N in water)
Phosphoric Acid (H₃PO₄)

SOLUTION PREPARATION

Diluent - 0.1 N HCI

The diluent was prepared by transferring 8.4 mL of HCl to a 1000 mL volumetric flask and diluting it to volume with water.

Mobile Phase A - 10 mM Na₂HPO₄, 10 mM Na₂B₄O₇ pH= 8.2

Solution was prepared by adding 1.4 g Na₂HPO₄ and 3.8 g of Na₂B₄O₇ to 1000 mL of water and stirring until completely dissolved. The pH was adjusted to 8.4 with 1.2 ml of HCI, followed by drop-wise addition of HCI until the pH was 8.2.

Mobile Phase B - 45:45:10 ACN-MeOH-Water

Solution was prepared by combining 450 mL Acetonitrile, 450 mL Methanol, and 100 mL Milli-Q water and mixing well.

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Injection diluent

Add 40 ul of concentrated H₃PO₄ to 10 ml of water

STANDARD PREPARATION

Amino Acid Mix A Stock Standard – Includes the Amino Acids Alanine, Arginine, Aspartic Acid, Cystine, Glutamic Acid, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Proline, Serine, Threonine, Tyrosine, and Valine

A mixed amino acid standard containing 17 amino acids was purchased from Agilent and arrived in 0.1N HCl. Calibration standards were then prepared from this mixed stock by diluting with 0.1 N HCl.

Supplemental mixed standard- Asparagine, Glutamine, Tryptophan, and Hydroxyproline

Mixed standard solution was prepared by weighing approximately 5 mg of Asparagine into a 50 mL volumetric flask. An aliquot of Glutamine, Tryptophan, and Hydroxyproline were added to the volumetric flask. 50 mL of diluent were added, and the flask was sonicated for 30 minutes.

Internal Standard

Solution was prepared by weighing 50 mg of Norvaline into a 50 mL volumetric flask. Brought to volume with diluent and mixed well.

SAMPLE PREPARATION

Sample Preparation

Sample was prepared by weighing ~700 mg of sample into a 50 mL volumetric flask. 50 mL of diluent were added, and the solution was sonicated for 30 minutes. The solution was diluted 10x with diluent. The solution was then filtered. 900 μL of filtrate were combined with 100 μL of IS and mixed well.

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INSTRUMENT PARAMETERS

Agilent 1100 Series HPLC System Instrument Detection **UV-Vis** Mobile Phase A 10 mM Na₂B₄O₇ pH= 8.2 Mobile Phase B 45:45:10 ACN-MeOH-Water **Gradient Program** Time (min) %A %B 0.0 98 2 2 0.5 98 20.0 57 43 20.1 0 100 0 100 23.5 23.6 98 2

Column Flow Rate Agilent Zorbax Eclipse Plus C18 RR, 150 x 4.6mm, 3.5 µm

2

98

1.5 mL/min

Detectior Settings:

UV Detection

OPA Amino Acids:

25

338 nm, 10 nm bandwidth (bw)

Reference 390, 20

FMOC-Amino Acids

262 nm, 16 nm bw

Reference 324, 8

Injection Volume

Injector Program

Column Temperature

40 °C

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Autosampler Injector Set-Up and Program:

Draw speed: 200 µL/min Eject speed: 200uL/min Draw Position: 0.0 mm Equilibration Time 2.0 sec

Vial 1 = Borate Buffer (HPLC vial, screw-cap)

Vial 2 = Injection Diluent

Vial 3 = OPA (GC vial w/ insert, crimp-cap)
Vial 4 = FMOC (GC vial w/ insert, crimp-cap)

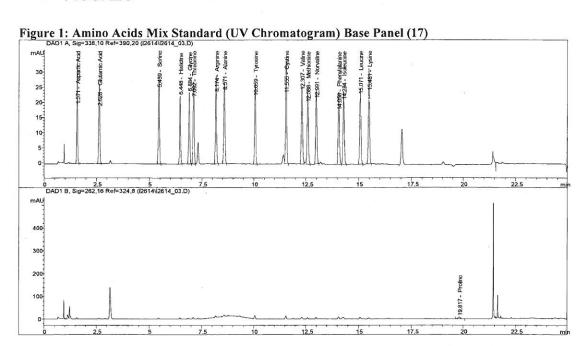
Vial 5 = Water (HPLC vial, no cap) Vial 6 = Water (HPLC vial, no cap) Vial 7 = Acetonitrile (HPLC vial, no cap)

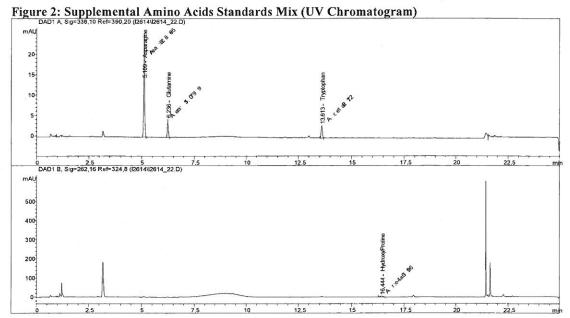
Row Action Needle wash in Vial 6, 1 times 2 Needle wash in Vial 5, 1 times 3 Needle wash in Vial 7, 1 times 4 Draw 2.5 µL from Vial 1 def. speed, def. offset 5 Draw 1.0 µL from Sample, def. speed, def. offset 6 Mix 3.5 µL "in seat", max. speed, 5 times 7 Wait 0.20 minutes 8 Draw 1.0 µL from Vial 3 9 Mix 4.5 µL in seat, max. speed, 10 times 10 Wait 1.00 min Draw 0.4 µL from Vial 4 def. speed, def. offset 11 12 Mix 4.9 µL in seat, max. speed, 10 times 13 Wait 1.00 min 14 Draw 32. µL from Vial 2 def. speed, def. offset 15 Mix 36.9 µL in seat, max. speed, 8 times 16 Inject Wait 0.20 min 17 18 Valve bypass

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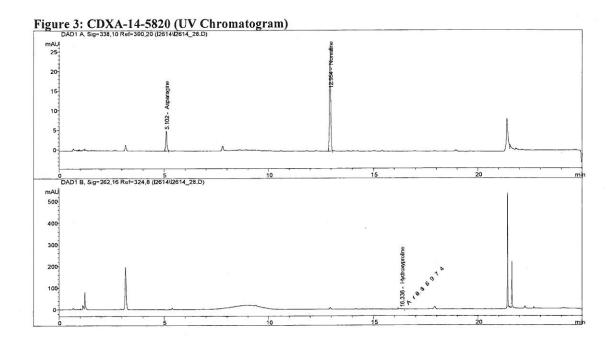
DATA

FIGURES





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REFERENCES

Analytical Method: 99.1-CD-5.0-000186 "Amino Acids by Pre-Column Derivitization HPLC."

| Laboratory Notebook | Page(s) |
|---------------------|---------|
| 385 | 145 |
| 362 | 156 |
| 402 | 6 |

REVISION HISTORY

| Revision Number | Document/Changes | | |
|-----------------|------------------|--|--|
| 00 | New report | | |

Case: 1:14-cv-09039 Document #: 1-1 Filed: 11/11/14 Page 13 of 19 PageID #:30



10005 Muirlands Blvd., Suite G | Irvine, CA 92618 Phone: (949) 419-0288 | Fax: (949) 419-0294 www.chromadex.com

Analytical Test Report

| - | | |
|----------|---------|-----------|
| Rarhat | Mansour | & SHOW |
| Daibat. | Manadui | OX COUCIU |

Customer:

PLLC

Report Number:

CDXA-ATR-6687-00

Address (City, State):

Detroit, MI

Project Number:

ORD68442

Purchase Order:

Not Provided

Date Received:

22-Sep-14

Date of Report:

09-Oct-14

Test Location:

Boulder, CO

Assay:

Creatine by HPLC

Part Number:

CDA-00100156-ATR

Prepared By:

Richard Vigil

09-Oct-14

Manager, Analytical Services

Date

Reviewed By:

Devon Cruz

09-Oct-14

Analyst I

Date

Approved By:

Sarah Garthe

09-Oct-14

Quality Assurance

Date

Signed original on file at CDXA

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SUMMARY

SAMPLE(S)

CVS Whey Protein Powder

Lot#

898224

CDXA#

CDXA-14-5820

RESULTS

Table 1 - Results CDXA-14-5820

| Analyte | Units | Spec. | Result A* | Result B* | Reporting Limit |
|----------|------------|-------|--------------|--------------|-----------------|
| Creatine | mg/serving | N/A | 3060 | 2250 | |

Serving Size: 39g

ND – Not detected above reporting Limit
BRL – Below reporting limit (compound detected below RL)

^{*}Sample was prepped multiple times due to high variability due to sample matrix. All results being reported.

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ANALYTICAL METHOD

STANDARD(S) All standards supplied by ChromaDex, unless otherwise specified.

Part #

Creatine

Sigma-C08780

LABORATORY SUPPLIES

Analytical Balance Ultrasonication Bath Assorted and Volumetric glassware Syringes and Syringe Filters HPLC/GC glass vials and caps

SOLVENTS AND REAGENTS

Acetonitrile (ACN) Tetrahydrofuran (THF) Milli-Q Water Formic Acid Ammonium Formate

SOLUTION PREPARATION

Mobile Phase A (2mM Ammonium Formate, pH 4.0)

Solution was prepared by adding 125 mg of Ammonium Formate to \sim 900 mL of Milli Q Water in a 1000mL volumetric flask and mixing well. The pH was adjusted to 4.0 using formic acid. The solution was then diluted to volume with Milli-Q water, mixed well and transferred to a 1 L mobile phase container.

Mobile Phase B (5% 2mM Ammonium Formate, pH 4.0 in ACN)

Solution was prepared by adding 50 mL of 2mM Ammonium Formate, pH 4 to 950 mL of ACN in a 1000mL volumetric flask and mixing well.

Diluent (50:50 Water:THF)

Diluent was prepared by adding 250 mL of Milli-Q water and 250 mL of THF into a 500 mL volumetric flask and mixing well.

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STANDARD PREPARATION

Stock Standard Solution

Approximately 6.5 mg of Creatine was weighed into a 25 mL volumetric flask. 25 mL of diluent was added and the solution sonicated for 15 minutes. The solution was allowed to re-equilibrate to room temperature and mixed well.

SAMPLE PREPARATION

Customer Sample(s) CDXA-14-5820

Sample was prepared by weighing approximately 160 mg of sample into a 25 mL volumetric flask. 25 mL of diluent was added and the flask sonicated for 15 minutes. The samples were filtered through a 0.45 µm PTFE filter into an HPLC vial for analysis.

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INSTRUMENT PARAMETERS

Instrument Agilent 1100 Series HPLC System Detection **UV-Vis** Mobile Phase A 2mM Ammonium Formate, pH 4.0 Mobile Phase B 5% 2mM Ammonium Formate, pH 4.0 in ACN **Gradient Program** Time (min) %A %B 0.0 0 100 5.0 0 100

 0.0
 0
 100

 5.0
 0
 100

 25.0
 45
 55

 30.0
 45
 55

 33.0
 0
 100

 45
 0
 100

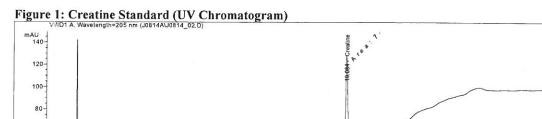
Column Cogent Diamond Hydride, 150 x 3mm x 4.0

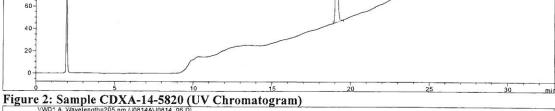
Flow Rate 1.0 mL/min UV Detection 205 nm Injection Volume 1 µL Temperature 30 °C

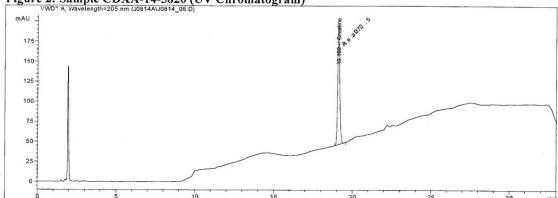
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DATA

FIGURES







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REFERENCES

ChromaDex SOP "Routine Laboratory Calculations"

70

Analytical Method: 99.1-CDXA-2.0-000318 "Creatine, Creatinol-O-Phosphate, and Creatinine by HPLC."

<u>Laboratory Notebook</u> <u>Page(s)</u>

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REVISION HISTORY

Revision Number

Document/Changes

00

New report