



about \$32 billion in revenue for just nutritional supplements alone in 2012, it is projected to double that by topping \$60 billion in 2021 according to the Nutritional Business Journal.”<sup>1</sup>

3. In order to reap substantial profits from the sales of nutritional supplements, many companies, including Defendant, look to cut corners to keep manufacturing costs low for their Product.

4. Defendant formulated, manufactured, warranted, advertised and sold the Product in Chicago, Illinois, throughout the State of Illinois, and throughout the United States.

5. Unbeknownst to Plaintiff and the members of the Class, who relied upon Defendant’s product labeling, the dietary supplements sold by Defendant did not contain consistent amounts of the sole active ingredient Standardized Extract Hypericin listed on their label.

6. Despite having knowledge that the Product’s labeling is deceptive, misleading, and constitutes a fraud on consumers, Defendant continues to advertise, distribute, label, manufacture, market, and sell the Product in a false, misleading, unfair, and/or deceptive manner.

7. Plaintiff and the Class seek actual damages, injunctive and declaratory relief, interest, costs, and reasonable attorneys’ fees.

## **II. JURISDICTION AND VENUE**

8. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). In the aggregate, Plaintiff’s 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 Defendant’s States of citizenship, as detailed below.

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<sup>1</sup> See <http://www.forbes.com/sites/davidlariviere/2013/04/18/nutritional-supplements-flexing-their-muscles-as-growth-industry/> (last visited on March 23, 2015.)

9. At all relevant times, the Product was, and continues to be, sold through numerous different online and brick/mortar retailers. Those retailers include CVS and Walgreens stores located in Chicago, Illinois, located throughout the State of Illinois, and located throughout the United States. There are tens of thousands of class members composing the proposed classes with tens of millions of dollars spent on the Product due to the far reaching distribution channels and high consumer demand for the herbal supplement Product.

10. This Court has personal jurisdiction over Defendant because Defendant conducts substantial business in the State of Illinois, such that Defendant has significant continuous and pervasive contacts with the State of Illinois. In particular, Defendant places its Product for sale at retail locations in Chicago, Illinois, specifically, as well as throughout the State of Illinois, including Walgreens and CVS stores.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1301(a)(2), 1391(b)(2), and 1391(c)(2) as: a substantial part of the events and/or omissions giving rise to the claims emanated from activities within this District, and Defendant conducts substantial business in this District.

### **III. PARTIES**

#### ***Plaintiff***

12. During the Class period, Plaintiff and the other members of the below-defined Classes purchased the Product through Walgreens and numerous other brick and mortar and online retail stores.

13. Plaintiff and Class Members suffered an injury in fact caused by the false, fraudulent, unfair, deceptive and misleading practices set forth in this Complaint. Plaintiff is a resident of the City of Lake Zurich, State of Illinois, and the events set forth in the Complaint

took place in July of 2015 when Plaintiff purchased the Product for his own use and not for resale from the retailer Walgreens.

***Defendant***

14. Defendant Nature's Bounty, Inc. is a corporation licensed in the State of Delaware, with a principal place of business address at 110 Orville Drive, Bohemia, New York 11716.

**IV. FACTUAL BACKGROUND**

15. Defendant labels and markets the Product in such a deceptive and misleading manner that Plaintiff and Class Members were deceived into purchasing Product that failed to provide consistent amounts of the active ingredient Standardized Extract Hypericin.

16. Health experts have long complained about the quality and safety of herbal supplements, which are exempt from the strict regulatory oversight applied to prescription and over-the-counter drugs. Putting aside questions as to the efficacy of these supplements, there have been longstanding questions as to whether they even contain the ingredients listed on their labels.

17. Although there is some regulatory framework under the Food, Drug and Cosmetic Act (the "Act") for herbal extracts, neither the Act nor the United States Food and Drug Administration have provided a legal or regulatory definition for "Standardized" extracts. Indeed, the National Institutes of Health, Office of Dietary Supplements, has confirmed that "no legal or regulatory definition exists for standardization in the United States as it applies to botanical dietary supplements."<sup>2</sup>

18. Despite this lack of oversight by governmental authority, the purpose of

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<sup>2</sup> See <http://ods.od.nih.gov/factsheets/BotanicalBackground-HealthProfessional/> (last visited March 23, 2015).

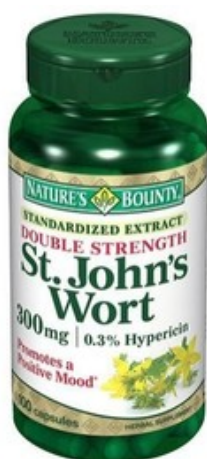
standardizing an extract is well known, as stated by NOW Foods, a leading dietary supplement manufacturer:

A standardized herbal extract is an herb extract that has one or more components present in a specific, guaranteed amount, usually expressed as a percentage. The intention behind the standardization of herbs is to guarantee that the consumer is getting a product in which the chemistry is consistent from batch to batch.<sup>3</sup>

19. Although there is no legal or regulatory definition, scientific journals have found: “Standardized guarantees the content of one or more active constituents and marker compounds.”<sup>4</sup>

20. When Plaintiff and Class Members were shopping for a St. John’s Wort product in the Standardized form, they expected to receive the “guaranteed” amount listed on the label based upon the general understanding of “Standardized.” Unfortunately, this is not what has happened.

21. Specifically, the label of Defendant’s St. John’s Wort Product predominantly features “Standardized Extract” on the front of the label:



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<sup>3</sup> See <http://www.nowfoods.com/Quality/Do-Supplements-Work/M043723.htm> (last visited March 23, 2015).

<sup>4</sup> See Garg, V., et al. *Facts about standardization of herbal medicine: a review*. Journal of Chinese Integrative Medicine, October 2012, Vol. 10, No. 10, 1077.

22. On the back of the label under the Supplement Facts section of the Product, the Defendant claims that the Product is “Standardized to contain 0.3% Hypericin, 0.9 mg”.

23. Unfortunately for Plaintiff and the Classes the Product actually contains substantially less amounts of Hypericin than the amount listed on the label, making it not “standardized.” See St. John’s Wort Product Testing, attached hereto as Exhibit A.

24. Further, the Product contains the claim “Promotes a Positive Mood”.

25. St. John's Wort is promoted as an anti-depressant herb that is commonly used for its neurological effects.

26. Defendant is fully aware that scientific literature has shown benefits with the Product, but at the lowest dosage of 0.9 mg per day, the exact amount claimed on the Product’s label. Also, because Defendant is the manufacturer of the Product, they are **fully aware** that they manufacture the Product **to contain less of the standardized extract than claimed**. Plaintiff, Class members, and a reasonable consumer would use this information, if Defendant disclosed it, in making the decision on whether to purchase Defendant’s Product. However, Defendant purposely omitted this material fact.

27. Plaintiff and the Class purchased and consumed the Product because they believed, based upon the misleading label, that it contained the Standardized ingredient listed on the label and that the quantity of such ingredient was accurately stated on the Product’ labels.

28. The name and labeling of the Product, as a “Standardized Extract,” was misleading to Plaintiff and the Class.

29. Plaintiff and the Class had a reasonable expectation that when purchasing the “Standardized Extract” Product, they would have purchased a Product with precise amounts of

the “Standardized Extract” contained within the Product.

30. Plaintiff and the Class would not have bought Defendant’s Standardized Extract St. John’s Wort Product if they had known that they had a significantly lower quantity of the Standardized Extract Hypericin than was stated on the Product label.

31. Plaintiff and Class Members were in fact misled by Defendant’s representations regarding the true nature of the Hypericin content and value.

32. The difference between the Product promised and the Product sold is significant. The amount of Hypericin provided has real impacts on the benefits provided to consumers by the Product, and the actual value of the Product themselves.

33. Defendant’s deceptive statements violate 21 U.S.C. § 343(a)(1), which deems food (including nutritional supplements) misbranded when the label contains a statement that is “false or misleading in any particular”.

34. Illinois has expressly adopted the federal food labeling requirements as its own and indicated that “[t]he 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.

35. 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 — (a) False or misleading label [i]f (1) its labeling is false or misleading in any particular.”

36. The Illinois Compiled Statutes incorporate the exact language of the Federal Food, Drug, and Cosmetic Act (“FDCA”) in 410 ILCS 620/11 by stating, “[a] food is misbranded - (a) If its labeling is false or misleading in any particular.”

37. Also, the Illinois Consumer Fraud Act provides protection for consumers when purchasing products, including Defendant's Product, by prohibiting "[u]nfair 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.

38. The introduction of misbranded food into interstate commerce is prohibited under the FDCA and all state parallel statutes cited in this Class Action Complaint.

39. Plaintiff and Class Members would have purchased other St. John's Wort products, if any at all, if they had not been deceived by the misleading labeling of the Product by Defendant.

## **V. CLASS ACTION ALLEGATIONS**

40. Plaintiff brings this action individually and as representatives of all those similarly situated pursuant to Federal Rule of Civil Procedure 23 on behalf of the below-defined Classes:

**National Class:** All persons in the United States that purchased the Product at any time during the four years before the date of filing of this Complaint to the present.

**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 at any time during the four years before the date of filing of this Complaint to the present.<sup>5</sup>

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<sup>5</sup> 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.*).



**Illinois Subclass:** All persons in the State of Illinois that purchased the Product at any time during the four years before the date of filing of this Complaint to the present.

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.

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 Hypericin content in the Product;
- b. Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Product are deceptive;
- c. Whether Defendant omitted material facts on the label of the Product;
- d. Whether Defendant's actions violate the State consumer fraud statutes invoked below;

e. Whether Defendant was unjustly enriched at the expense of the Plaintiff and Class Members; and

f. 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.

47. **Insufficiency of Separate Actions – Federal Rule of Civil Procedure 23(b)(1).** 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. CHOICE OF LAW**

### ***The Substantive Law of Illinois Applies to the Claims of the National Class***

50. Illinois' substantive laws apply to the claims asserted by the proposed National Class, as set forth below, because Plaintiff properly brings this action in this District. A United

States District Court sitting in diversity presumptively applies the substantive law of the state in which it sits. *Land v. Yamaha Motor Corp., U.S.A.*, 272 F. 3d 514, 516 (7th Cir. 2001).

51. The Court may constitutionally apply Illinois' substantive laws to Plaintiff's claims and the claims of the National Class under the Due Process Clause of the Fourteenth Amendment, § 1, and the Full Faith and Credit Clause, Article IV, § 1, of the United States Constitution. The claims asserted by Plaintiff contain significant contact, or a significant aggregation of contacts, to ensure an adequate state interest and supports the choice of Illinois state law as just and reasonable.

52. Defendant conducts substantial business in Illinois, providing Illinois with an interest in regulating Defendant's conduct under Illinois laws. Defendant's decision to regularly conduct business in Illinois and avail themselves of Illinois' laws render the application of Illinois law to the claims at hand constitutionally permissible.

53. The injury to Plaintiff and to a significant number of members of the proposed Class by virtue of the conduct alleged, occurred in Illinois. Plaintiff resides in Illinois and purchased Defendant's Product in Illinois. A substantial number of the proposed Nationwide Class reside in Illinois and purchased Defendant's Product in Illinois.

54. The application of Illinois law to the members of the proposed National Class is also appropriate under Illinois' choice-of-law rules, because Illinois has significant contacts with the claims of the Plaintiff and each of the members of the proposed National Class.

## **VII. CLAIMS ALLEGED**

### **COUNT I**

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

55. Plaintiff incorporates paragraphs 1-54 as if fully set forth herein.

56. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class<sup>6</sup> prohibit the use of unfair or deceptive business practices in the conduct of trade or commerce.

57. Defendant intended that Plaintiff and each of the other members of the Consumer Fraud Multi-State Class would rely upon its 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 and each of the other members of the Consumer Fraud Multi-State Class 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 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)**

60. Plaintiff incorporates paragraphs 1-54 as if fully set forth herein.

61. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1, *et seq.*, 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.

62. Defendant intended that Plaintiff and each of the other members of the Illinois Subclass would rely upon its deceptive conduct, and a reasonable person would in fact be misled by this deceptive conduct.

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<sup>6</sup> 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.*).

63. 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 Illinois Subclass have sustained damages in an amount to be proven at trial.

64. 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)**

65. Plaintiff incorporates paragraphs 1-54 as if fully set forth herein.

66. Plaintiff and the other members of the National Class conferred benefits on Defendant by purchasing the Product.

67. Defendant has been unjustly enriched in retaining the revenues derived from Plaintiff and the other members of the National Class' purchase of the Product. 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.

68. 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)**

69. Plaintiff incorporates paragraphs 1-54 as if fully set forth herein.

70. 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 include the promises and affirmations of fact made by Defendant on the Product' 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.

71. Defendant purports through its advertising, labeling, marketing and packaging to create an express warranty that the Product contained St. John's Wort "Standardized Extract".

72. Defendant was aware that the Product it manufactured and Plaintiff purchased did not contain consistent amounts of its sole active ingredient, Standardized Extract Hypericin, as listed on Defendant's labels. Indeed, Defendant is a sophisticated entity that: (a) manufactured the Product; (b) has been in business for decades; (c) touts it "dedication to quality, consistency, and scientific research"; (d) subjected the Product to "numerous quality tests and assays" to "verify purity and full potency"; (e) sold the mislabeled Products despite its test results; and (f) collected tens of millions of dollars via sales of the Product.

73. Plaintiff and the National Class performed all conditions precedent to Defendant's liability under this contract when they purchased the Product.

74. Defendant breached express warranties about the Product and its qualities because Defendant's statements about the Product were false and the Product do not conform to Defendant's affirmations and promises described above.

75. 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.

76. 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.

#### **VIII. DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury of all claims in this complaint so triable.

#### **IX. REQUEST FOR RELIEF**

WHEREFORE, Plaintiff, individually and on behalf of the other members of the Classes proposed in this Complaint, respectfully request that the Court enter judgment as follows:

- A. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiff as Class Representative and appointing the undersigned counsel as Class Counsel for the Classes;
- B. Ordering Defendant to pay actual damages to Plaintiff and the other members of the Classes;
- C. Ordering Defendant to pay punitive damages, as allowable by law, to Plaintiff and the other members of the Classes;
- D. Ordering Defendant to pay statutory damages, as provided by the applicable state consumer protection statutes invoked above, to Plaintiff and the other members of the Classes;
- E. Ordering Defendant to pay attorneys' fees and litigation costs to Plaintiff and the other members of the Classes;



- F. Ordering Defendant to pay both pre- and post-judgment interest on any amounts awarded;
- G. Leave to amend this Complaint to conform to the evidence presented at trial; and
- H. Ordering such other and further relief as may be just and proper.

Dated: October 13, 2016

Respectfully submitted,

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***Counsel for Plaintiff  
and the Proposed Putative Classes***

# EXHIBIT A



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

## Analytical Results Sheet

Customer: Barbat, Mansour & Suci PLLC  
 Address (City, State): Detroit, MI

Report Number: CDXA-ARS-24300-00  
 Project Number: ORD73888

Sample Name: Nature's Bounty St. John's Wort  
 Sample Lot: 935064-05  
 CDXA Number: CDXA-15-3566

Date Received: 05-May-15  
 Purchase Order: N/A

Assay: Hypericins by HPLC  
 Part Number: CDA-00018505-ARS  
 Method: ALC140A for Hypericin

Date of Report: 21-May-15  
 Page: 1 of 2  
 Test Location: Sub41

| Analyte                                   | Units      | Spec. | Result | Reporting Limit |
|-------------------------------------------|------------|-------|--------|-----------------|
| Hypericin                                 | mg/serving | N/A   | 0.355  | --              |
| PseudoHypericin (calculated as hypericin) | mg/serving | N/A   | 0.223  | --              |
| Total Hypericins                          | mg/serving | 0.9   | 0.578  | --              |

Serving Size: 1 capsule

*Signed original on file at CDXA*

This product analysis is subject to our "Standard Terms and Conditions for the Purchase and Sale of ChromaDex Products and or Services," a copy of which has been provided to our client and is incorporated herein by this reference. As more specifically set forth therein, this product analysis is for the benefit of our client only, may not be relied upon by any other party without our prior written consent, relates solely to the sample(s) provided to us by our client and therefore cannot be applied to any other material or sample. Unless otherwise noted, samples were received in acceptable condition and analyzed as received. This document may not be printed in part without the explicit permission of ChromaDex.

ND – Not Detected

BRL – Below reporting limit (compound detected below RL)



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

## Form 1A: Initial Investigation of Out of Specification (OOS) Results

### Summary

Customer: Barbat, Mansour & Suci PLLC  
 Sample: CDXA-15-3566  
 Sample Name: Nature's Bounty St. John's Wort  
 Lot Number: 935064-05

Date: 21-May-15  
 OOS #: OOS-15-0765

Report: CDXA-ARS-24300-00  
 ORD #: ORD73888

Assay: Hypericins by HPLC  
 Part Number: CDA-00018505-ARS  
 Method: ALC140A for Hypericin

Analyst: Sub41

Review: Kristie Kokeny

|                       |                                          |
|-----------------------|------------------------------------------|
| <b>OOS Result:</b>    | <b>0.578 mg/serving Total Hypericins</b> |
| <b>Specification:</b> | <b>0.9 mg/serving Total Hypericins</b>   |

### Preliminary Investigation

The OOS investigation should be conducted by the analyst and the analytical manager or group leader. If there is any reason to invalidate the data, document the reason below, invalidate the result and repeat the analysis.

| Checklist                                                   | Yes                                 | No                                  | Comments |
|-------------------------------------------------------------|-------------------------------------|-------------------------------------|----------|
| Laboratory Control Sample (LCS) within Limits Documentation | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Calculation Error                                           | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |          |
| Transcription Error                                         | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |          |
| Methodology                                                 |                                     |                                     |          |
| Correct SOP Followed                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Deviated from SOP                                           | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |          |
| Samples, Standards, Reagents                                |                                     |                                     |          |
| Check of Glassware Used                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Daily Balance Calibration Performed                         | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Instrument                                                  |                                     |                                     |          |
| Calibration OK                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Continuing Calibration Passed                               | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |
| Instrument Parameters OK                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |          |

### Comments

Is data valid or invalid, give justification?

Sample or sampling issues?

### Approval

If there is no reason to suspect the analyst's work the analytical manager will sign below. This form will be sent to the client so that they may discuss possible sample problems, re-sampling, and re-testing.

Manager/Designee  
 Signature:

Kristie Kokeny

Digitally signed by Kristie Kokeny  
 DN: cn=Kristie Kokeny, o=Chromadex, Inc.,  
 ou=Quality Assurance,  
 email=kristie.k@chromadex.com, c=US  
 Date: 2015.05.21 16:20:14 -06:00

### Re-testing of Results (To be completed by customer)

After the client reviews the data, they are to decide if they would like the sample retested. The retest must be requested within 10 business days of the reports initial release. If the sample is retested, and the results are still OOS, the client will be billed for the retest. If the retest yields results that meet the client's specifications, the client will not be billed.

If re-test is requested, client/authorized sales representative should sign below and return this form to the laboratory. Form 2 will be used to document the retest results and assignable cause. Results for an OOS re-run will be released within 5 business days.

Client Authorization: \_\_\_\_\_

Date: \_\_\_\_\_

PO Number: \_\_\_\_\_

CDX Work Order: \_\_\_\_\_