

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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<i>In re Elysium Health—ChromaDex Litigation.</i>	:	Civil Action No. 1:17-cv-07394 (CM)
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**CHROMADEX, INC.’S ANSWER TO
ELYSIUM HEALTH, INC.’S COUNTERCLAIMS**

ChromaDex, Inc. (“ChromaDex”), by and through its undersigned attorneys, hereby submits this Answer in response to the numbered paragraphs of Elysium Health, Inc.’s (“Elysium”) Counterclaims (Dkt. No. 45), as follows:

NATURE OF THE CASE

1. Paragraph 1 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 1.

2. ChromaDex denies the allegations of ¶ 2, except admits that the molecule NR was discovered in the 1940s.

3. ChromaDex denies the allegations of ¶ 3.

4. ChromaDex denies the allegations of ¶ 4, and refers the Court to the website for Tru Niagen, which is maintained by ChromaDex, for its complete and accurate contents.

5. ChromaDex denies the allegations of ¶ 5, except admits that it maintains a website for Tru Niagen and refers the Court to that website, for its complete and accurate contents.

6. ChromaDex denies the allegations of ¶ 6.

7. ChromaDex denies the allegations of ¶ 7.

8. ChromaDex admits that (a) NDIN 882 recommended that daily intake of Niagen not exceed 180 mg; (b) NDIN 1062 recommended that daily intake of Niagen not exceed 300 mg; and (c) at all times in which ChromaDex sold its consumer product, Tru Niagen, the ingredient Niagen was “Generally Recognized As Safe.” ChromaDex denies the allegations of ¶ 8 in all other respects.

9. ChromaDex denies the allegations of ¶ 9.

10. ChromaDex denies the allegations of ¶ 10, except is without sufficient knowledge or information to form a belief as to what the FDA considered in its review process.

11. ChromaDex denies the allegations of ¶ 11, except admits that the statement on the Tru Niagen website which states that “Niagen increases NAD by 60%” is qualified by a footnote, which reads “[o]n average at 1000 mg / day for 6 days in 21 people.” ChromaDex refers the Court to the Tru Niagen website, for its complete and accurate contents.

12. ChromaDex denies the allegations of ¶ 12.

13. ChromaDex denies the allegations of ¶ 13.

14. ChromaDex denies the allegations of ¶ 14, except admits that Elysium sells a product called Basis, which contains NR and other ingredients.

15. ChromaDex admits that (a) ChromaDex has tested Elysium’s product on occasion; and (b) Elysium sells a product called Basis, which contains NR and other ingredients.

16. ChromaDex denies the allegations of ¶ 16.

17. ChromaDex denies the allegations of ¶ 17, except is without sufficient knowledge or information to form a belief as to the testing which Basis purportedly underwent.

18. Paragraph 18 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 18.

19. ChromaDex denies the allegations of ¶ 19.

20. ChromaDex denies the allegations of ¶ 20.

21. ChromaDex denies the allegations of ¶ 21.

22. Paragraph 22 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 22.

FACTUAL ALLEGATIONS

23. ChromaDex admits that (a) Tru Niagen contains NR; (b) Basis contains NR and other ingredients; (c) ChromaDex markets Tru Niagen nationwide; (d) on information and belief, Elysium markets Basis nationwide; (e) Elysium is a former customer of ChromaDex; (f) Elysium currently obtains NR from an unknown source; (g) Tru Niagen is sold directly to consumers; and (h) ChromaDex and Elysium are currently competitors. ChromaDex denies the allegations of ¶ 23 in all other respects.

24. ChromaDex admits that (a) ChromaDex markets Tru Niagen nationwide; (b) ChromaDex sells Tru Niagen via an interactive website, which has the URL www.truniagen.com; (c) the Tru Niagen website contains links which graphically display the words "Buy Now"; (d) consumers can purchase individual bottles or bottle packs of Tru Niagen, or they can purchase a subscription; and (e) ChromaDex has sold Tru Niagen to clients in New York. ChromaDex denies the allegations of ¶ 24 in all other respects.

25. Paragraph 25 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 25.

26. ChromaDex admits that the “FAQ” page of the Tru Niagen website states that “[i]n 2004, Charles Brenner PhD discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside) that is a natural precursor to NAD.” ChromaDex denies the allegations of ¶ 26 in all other respects, including the manner and context in which Elysium characterizes ChromaDex’s statements.

27. ChromaDex admits that the “Our Product” section of the Tru Niagen website states that “Tru Niagen is a specialized form of vitamin B3 discovered by our Chief Scientific Advisor Charles Brenner, PhD and developed specifically to increase NAD more effectively than any other B3 before it.” ChromaDex denies the allegations of ¶ 27 in all other respects, including the manner and context in which Elysium characterizes ChromaDex’s statements.

28. ChromaDex admits that (a) Brenner did not discover the molecule NR; and (b) Brenner made important discoveries relating to the process by which NR is used to make NAD+.

29. ChromaDex refers the Court to its responses to the allegations of ¶ 28, and otherwise denies the allegations of ¶ 29.

30. ChromaDex denies the allegations of ¶ 30.

31. ChromaDex denies the allegations of ¶ 31, except admits that the molecule NR was discovered in the 1940s.

32. Paragraph 32 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 32.

33. Paragraph 33 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 33.

34. ChromaDex denies the allegations of ¶ 34, and refers the Court to the Tru Niagen website, for its complete and accurate contents.

35. ChromaDex admits that the Tru Niagen website states that (a) "NR is a patented ingredient, only sold as NIAGEN®. ChromaDex holds the patent rights to NR, and sells the ingredient to consumers as TRU NIAGEN®"; and (b) "If you are taking or plan to purchase an NR supplement, look at your label to ensure 'NIAGEN®' appears under the 'Supplement Facts.'" ChromaDex denies the allegations of ¶ 35 in all other respects, including the manner and context in which Elysium characterizes ChromaDex's statements, and refers the Court to the Tru Niagen website, for its complete and accurate contents.

36. ChromaDex denies the allegations of ¶ 36, and refers the Court to the Tru Niagen website, for its complete and accurate contents.

37. Paragraph 37 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 37.

38. ChromaDex denies the allegations of ¶ 38, except admits that (a) Basis contains NR and other ingredients; and (b) ChromaDex and Elysium are currently competitors.

39. ChromaDex denies the allegations of ¶ 39, except admits that (a) Elysium sells a product called Basis, which contains NR and other ingredients; and (b) ChromaDex has tested Elysium's product on occasion.

40. Paragraph 40 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 40.

41. Paragraph 41 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 41.

42. ChromaDex denies the allegations of ¶ 42.

43. ChromaDex denies the allegations of ¶ 43, except admits that ChromaDex sent two NDI notifications and a GRAS finding to the FDA, related to Niagen, and refers the Court to the Tru Niagen website, for its complete and accurate contents.

44. ChromaDex denies the allegations of ¶ 44.

45. ChromaDex denies the allegations of ¶ 45, except is without sufficient knowledge or information to form a belief as to what the FDA considered in its review process.

46. ChromaDex denies the allegations of ¶ 46.

47. ChromaDex admits the allegations of ¶ 47.

48. ChromaDex refers the Court to its responses to the allegations of ¶¶ 35 and 43. ChromaDex denies the allegations of ¶ 48 in all other respects, including the manner and context in which Elysium characterizes ChromaDex's statements.

49. ChromaDex denies the allegations of ¶ 49.

50. Paragraph 50 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 50.

51. ChromaDex admits that it submitted an NDI notification on or about August 24, 2015, and supplemented its notification on or about October 13, 2015 and October 30, 2015. ChromaDex denies the allegations of ¶ 51 in all other respects, and refers the Court to the documents referenced therein, for their complete and accurate contents.

52. ChromaDex admits that it received correspondence from the FDA on or about November 3, 2015, which stated in part: “Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342.” ChromaDex denies the allegations of ¶ 52 in all other respects, including the manner and context in which Elysium characterizes the FDA’s written statements, and refers the Court to the document referenced therein, for its complete and accurate contents.

53. ChromaDex admits that (a) it submitted an NDI notification on or about December 27, 2017; and (b) it received correspondence from the FDA on or about March 7, 2018, which stated in part: “Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. § 342.” ChromaDex denies the allegations of ¶ 53 in all other respects, including the manner and context in which Elysium characterizes the FDA’s written statements, and refers the Court to the document referenced therein, for its complete and accurate contents.

54. ChromaDex admits that (a) it operates a regulatory consulting business, called Spherix Consulting, Inc.; and (b) Spherix Consulting, Inc. offers services related to NDI notifications. ChromaDex denies the allegations of ¶ 54 in all other respects.

55. Paragraph 55 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 55.

56. ChromaDex admits that it submitted on March 8, 2016, through Spherix Consulting, Inc., a correspondence stating that a panel of expert toxicologists found Niagen to be “Generally Recognized As Safe.” ChromaDex denies the allegations of ¶ 56 in all other respects, and refers the Court to this correspondence, for its complete and accurate contents.

57. ChromaDex admits that, on or about August 3, 2016, the FDA sent a correspondence to ChromaDex, which stated in part that: “Based on the information provided by ChromaDex, as well as other information available to FDA, the agency has no questions at this time regarding ChromaDex’s conclusion that NR is GRAS under the intended conditions of use.” ChromaDex denies the allegations of ¶ 57 in all other respects, and refers the Court to this correspondence, for its complete and accurate contents.

58. ChromaDex admits that, on or about August 3, 2016, the FDA sent a correspondence to ChromaDex, which stated in part that: (a) “In its review of ChromaDex’s notice that NR is GRAS for the intended uses, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing NR. Accordingly, this response should not be construed to be a statement that foods that contain NR, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll)”; and (b) “The agency has not, however, made its own determination regarding the GRAS status of the subject use of NR. As always, it is the continuing responsibility of ChromaDex to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory

requirements.” ChromaDex denies the allegations of ¶ 58 in all other respects, and refers the Court to this correspondence, for its complete and accurate contents

59. ChromaDex denies the allegations of ¶ 59.

60. ChromaDex admits that (a) it operates a regulatory consulting business, called Spherix Consulting, Inc.; and (b) Spherix Consulting, Inc. offers services related to GRAS notices. ChromaDex denies the allegations of ¶ 60 in all other respects.

61. Paragraph 61 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 61.

62. ChromaDex denies the allegations of ¶ 62.

63. ChromaDex denies sufficient knowledge or information to form a belief as to the truth of the allegations of ¶ 63.

64. ChromaDex denies sufficient knowledge or information to form a belief as to the truth of the allegations of ¶ 64.

65. ChromaDex denies sufficient knowledge or information to form a belief as to the truth of the allegations of ¶ 65.

66. Paragraph 66 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 66.

67. ChromaDex admits that (a) NDIN 882 recommended that daily intake of Niagen not exceed 180 mg; (b) NDIN 1062 recommended that daily intake of Niagen not exceed 300 mg; and (c) at all times in which ChromaDex sold its consumer Niagen product, Tru Niagen,

Niagen was also “Generally Recognized As Safe.” ChromaDex denies the allegations of ¶ 67 in all other respects.

68. ChromaDex denies the allegations of ¶ 68.

69. ChromaDex admits that, in general, the NDI and GRAS processes are not intended to test or review efficacy of an ingredient or food. ChromaDex denies the allegations of ¶ 69 in all other respects.

70. Paragraph 70 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 70.

71. Paragraph 71 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 71.

72. ChromaDex admits the allegations of ¶ 72.

73. ChromaDex denies the allegations of ¶ 73, including the manner and context in which Elysium characterizes ChromaDex’s statements, except admits that the statement on the Tru Niagen website which states that “Niagen increases NAD by 60%” is qualified by a footnote, which reads “[o]n average at 1000 mg / day for 6 days in 21 people.” ChromaDex refers the Court to the Tru Niagen website, for its complete and accurate contents.

74. ChromaDex admits that the daily recommended intake of Niagen is 250 mg. ChromaDex denies the allegations in ¶ 74 in all other respects.

75. ChromaDex denies sufficient knowledge or information to form a belief as to the truth of the allegations of ¶ 75, as they relate to a review on Amazon.com. ChromaDex denies the allegations of ¶ 75, in all other respects.

76. Paragraph 76 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 76.

77. ChromaDex denies the allegations of ¶ 77, except denies sufficient knowledge or information to form a belief as to the truth of Elysium's assertions regarding Basis.

78. Paragraph 78 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 78.

79. Paragraph 79 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 79.

80. Paragraph 80 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 80.

81. ChromaDex denies the allegations of ¶ 81, except admits that at the bottom of the pages of the Tru Niagen website, it states "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

82. Paragraph 82 contains Elysium's characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 82.

83. ChromaDex admits (a) it is aware of the blog called "Right of Assembly"; (b) its personnel have met the individual who, upon information and belief, controls the "Right of

Assembly” blog, on one occasion. ChromaDex denies the allegations in ¶ 83 in all other respects.

84. ChromaDex denies the allegations in ¶ 84.

85. ChromaDex denies sufficient knowledge or information to form a belief as to the truth of the allegations of ¶ 85.

86. Paragraph 86 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 86.

87. ChromaDex denies the allegations of ¶ 87, except denies sufficient knowledge or information to form a belief as to the truth of Elysium’s assertions regarding the text of the blog posts described therein.

88. ChromaDex admits the allegations of ¶ 88.

89. ChromaDex denies the allegations of ¶ 89.

90. ChromaDex denies the allegations of ¶ 90, except denies sufficient knowledge or information to form a belief as to the truth of Elysium’s assertions regarding the text of the reviews described therein.

91. Paragraph 91 contains Elysium’s characterizations of its claims, legal assertions, and conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 91.

FIRST COUNTERCLAIM FOR RELIEF

(FALSE ADVERTISING UNDER 15 U.S.C. § 1125(a))

92. ChromaDex incorporates its responses to each and every allegation, as set forth above.

93. Paragraph 93 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 93.

94. Paragraph 94 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 94.

95. Paragraph 95 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 95.

96. Paragraph 96 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 96.

SECOND COUNTERCLAIM FOR RELIEF

(FEDERAL UNFAIR COMPETITION UNDER 15 U.S.C. § 1125(a))

97. ChromaDex incorporates its responses to each and every allegation, as set forth above.

98. Paragraph 98 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 98

99. Paragraph 99 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 99.

100. Paragraph 100 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 100.

THIRD COUNTERCLAIM FOR RELIEF

(DECEPTIVE PRACTICES UNDER NEW YORK GENERAL BUSINESS LAW § 349)

101. ChromaDex incorporates its responses to each and every allegation, as set forth above.

102. Paragraph 102 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 102.

103. Paragraph 103 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 103.

104. Paragraph 104 asserts argument and legal conclusions to which no response is required. To the extent a response is required, ChromaDex denies the allegations in ¶ 104.

PRAYER FOR RELIEF

The Prayer for Relief describes the relief sought by Elysium and does not require a responsive pleading. To the extent a response is required, ChromaDex hereby denies that Elysium is entitled to any relief whatsoever.

DEFENSES AND AFFIRMATIVE DEFENSES

Unless otherwise specified, all defenses and affirmative defenses are asserted as to all counterclaims. Assertion by ChromaDex of any affirmative defense or any other defense shall not be deemed a concession that ChromaDex has the burden of proof with respect to any of them.

FIRST AFFIRMATIVE DEFENSE

The Counterclaims fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because Elysium lacks standing to assert them.

THIRD AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's conduct and statements did not misrepresent the nature, characteristics or qualities of its goods, services and/or commercial activities.

FOURTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's conduct and statements have not resulted in any injuries, damages, or harm, and have not deceived the public.

FIFTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, by the First Amendment to the Constitution of the United States.

SIXTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's statements, as alleged by Elysium, were not false or misleading statements of fact.

SEVENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's statements, as alleged by Elysium, were not directed at consumers.

EIGHTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in part, because any purported violations did not occur in New York.

NINTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's statements, as alleged by Elysium, were not commercial advertising or promotion.

TENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex's statements did not injure the public at large.

ELEVENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, by the equitable doctrines of waiver, laches, estoppel, acquiescence, or unclean hands.

TWELFTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because Elysium's injuries or damages, if any, were directly and proximately caused and contributed to by Elysium's own conduct, acts, omissions, activities, carelessness, recklessness, negligence, and/or intentional misconduct.

THIRTEENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because ChromaDex is not liable for the acts of others over whom it has no control.

FOURTEENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because any representations which may have been made by ChromaDex were based on information supplied to ChromaDex by other sources, which information ChromaDex believed to be true, and/or were otherwise made in good faith and with genuine belief that they had a reasonable factual and historical basis.

FIFTEENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because the statements upon which Elysium bases its claims are puffery that cannot serve as a basis to establish liability against ChromaDex.

SIXTEENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, by the applicable statutes of limitations.

SEVENTEENTH AFFIRMATIVE DEFENSE

The Counterclaims are barred, in whole or in part, because they are duplicative.

RESERVATION OF RIGHTS

ChromaDex reserves the right to assert additional defenses that may present themselves during these proceedings and hereby reserves the right to amend its Answer to assert any such defenses.

PRAYER FOR RELIEF

WHEREFORE, ChromaDex prays for judgment as follows:

1. For judgment in favor of ChromaDex on the Counterclaims;
2. For attorneys' fees and costs incurred to the extent permitted by law; and
3. For such other and further relief as this Court may deem just and proper.

Dated: New York, New York
November 2, 2018

COOLEY LLP

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