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*Attorneys for Defendant ChromaDex, Inc.*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH**

_____	:	
Novex Biotech, LLC, a Utah Limited Liability Company,	:	<b>CHROMADEX INC.’S ANSWER AND COUNTERCLAIMS AGAINST NOVEX BIOTECH LLC</b>
	:	
Plaintiff,	:	<b>DEMAND FOR A JURY TRIAL</b>
	:	
v.	:	Case No. 2:19-cv-00271-JNP-PMW
	:	
ChromaDex, Inc., a California Corporation and Does 1-10,	:	The Honorable Judge Jill N. Parrish
	:	
Defendant.	:	Magistrate Judge Paul M. Warner
_____	:	

**ANSWER**

Defendant ChromaDex, Inc. (“ChromaDex”), for its answer, defenses, and counterclaim to the complaint filed by plaintiff Novex Biotech, LLC (“Novex”), hereby states as follows:

**SUMMARY OF ALLEGATIONS**<sup>1</sup>

Denied.

**PARTIES**

1. Admitted.
2. Admitted.
3. ChromaDex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

**JURISDICTION AND VENUE**

4. ChromaDex admits that Novex purports to bring an action for “false advertising and unfair competition under the Lanham Act”. ChromaDex otherwise denies the allegations in this paragraph.

5. The allegations in this paragraph consist only of legal conclusions to which no response is required. To the extent a response is required, ChromaDex admits the allegations in this paragraph.

6. ChromaDex admits that it is subject to specific personal jurisdiction in this Court for causes of action related to sales of its products in Utah. ChromaDex otherwise denies the allegations in this paragraph.

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<sup>1</sup> For purposes of its answer, ChromaDex has copied the headings Novex used in its complaint. To the extent the headings are intended to be factual allegations, ChromaDex denies all such allegations.

**GENERAL ALLEGATIONS**

**Novex's Product**

7. ChromaDex admits that Novex markets and sells a product called “Oxydrene Elite.” ChromaDex otherwise denies the allegations in this paragraph.

8. Denied.

9. ChromaDex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

10. Admitted.

11. Admitted.

12. ChromaDex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

**ChromaDex's False and Misleading Advertising<sup>2</sup>**

13. ChromaDex admits it sells Tru Niagen. ChromaDex otherwise denies the allegations in this paragraph.

14. Admitted.

15. Admitted.

16. ChromaDex admits that the quoted phrases, “[a]ll four peer-reviewed published clinical trials confirm Niagen is a safe and efficient way of increasing NAD levels in humans” and “Tru Niagen is a unique form of vitamin B3 clinically proven to safely increase your cell’s ability to make energy, with NAD”, have appeared on some marketing materials. ChromaDex otherwise denies the allegations in this paragraph.

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<sup>2</sup> ChromaDex denies that its advertisements are false or misleading.

17. Admitted.

18. Denied.

19. Denied.

20. Chromadex admits that the quoted words appear in its New Dietary Ingredient Notification submission to the FDA. ChromaDex denies that this paragraph fully captures the substance or content of the submission as a whole, and otherwise denies the allegations in this paragraph.

21. Denied.

22. Denied.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Denied.

28. Denied.

29. Denied.

**FIRST CLAIM FOR RELIEF**

**(False Advertising in Violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B))**

30. ChromaDex incorporates its answers set forth above.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

**SECOND CLAIM FOR RELIEF**

**(Unfair Competition in Violation of Lanham Act, 15 U.S.C. § 1125(a)(1))**

39. ChromaDex incorporates its answers set forth above.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

**DEFENSES**

ChromaDex sets forth the following affirmative and other defenses to Novex's Complaint. In so doing, ChromaDex does not assume the burden of proving any fact, issue, proposition, or element of a cause of action where such burden properly belongs to Novex.

**Defense #1**

(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted under 15 U.S.C. 1125(a)(1), separate and apart from its putative claim for false advertising under 15 U.S.C. 1125(a)(1)(B), because Novex has not alleged that any act by ChromaDex is likely to cause confusion, to cause mistake, or to deceive as to the affiliation, connection, or association of ChromaDex's goods or services.

**Defense #2**

(Truth and First Amendment)

The Complaint fails to state a claim upon which relief can be granted because ChromaDex's statements are true, are protected by the First Amendment, and/or are otherwise permitted by law.

**Defense #3**

(Unclean Hands)

All of Novex's claims are barred by the doctrine of unclean hands, including without limitation because Novex engaged in false advertising of its own products.

**Defense #4**

(Additional Defenses)

ChromaDex presently has insufficient knowledge or information upon which to form a belief whether it may have additional, unstated defenses. On that basis, ChromaDex reserves the right to amend its answer to assert additional defenses in the event discovery indicates that additional defenses are appropriate.

## **COUNTERCLAIMS**

Counterclaim Plaintiff ChromaDex, Inc. (“ChromaDex,”), by and through its counsel of record, hereby brings these Counterclaims for false advertising and unfair competition against Counterclaim Defendant Novex Biotech, LLC (“Novex”), and alleges as follows:

### **NATURE OF THE ACTION**

1. ChromaDex is a leading health and wellness company. NIAGEN, ChromaDex’s flagship product, is revolutionizing the way people age by increasing nicotinamide adenine dinucleotide (NAD) in the body. NAD is a vital resource for cellular energy and repair. The scientific evidence of safety and efficacy for NIAGEN is extensive.

2. ChromaDex has dozens of studies showing that NIAGEN is safe. ChromaDex has submitted to the Food and Drug Administration (“FDA”) a safety submission proving that the ingredient is safe in dietary supplement form (known as a New Dietary Ingredient Notification). ChromaDex has also submitted data to the FDA showing that the ingredient is safe to use in foods. Following this submission, the FDA responded with a “no objection” letter confirming that the active ingredient in NIAGEN is “Generally Recognized As Safe.”

3. As to efficacy, ChromaDex has four robust and peer reviewed human clinical trials proving that NIAGEN works. That is the gold standard, far exceeding all legal and regulatory requirements for a dietary supplement. In total, ChromaDex also has over 140 research collaborations with leading universities and hospitals around the world in support of NIAGEN.

4. The dietary ingredient in NIAGEN is nicotinamide riboside (“NR”). ChromaDex protects this novel ingredient with 20 patents worldwide.

5. The scientific evidence demonstrates that NIAGEN increases NAD in the body.

Increased NAD can:

- *maintain healthy mitochondria*
- *promote cellular repair*
- *promote healthy aging*
- *give cells an essential tool for energy creation*

6. As a science-based company, ChromaDex is careful to ensure that its claims are supported by competent and reliable scientific evidence, as required by law.

7. Beyond its scientific substantiation, ChromaDex also meets the FDA's other regulatory requirements. It has submitted claim notification letters to the FDA and it maintains good manufacturing practices.

8. Novex, on the other hand, sells a dietary supplement called Oxydrene Elite. Novex makes outlandish claims for this product, including that it is "proprietary" and a "revolutionary new compound" that "maximizes" "blood oxygenation, muscle recovery and athletic performance" and even that it can make people "run faster," "cut" time off races, and enable "peak aerobic activity."

9. But in reality, Oxydrene Elite contains nothing more than small amounts of commodity household ingredients that provide none of the health benefits claimed. It is not revolutionary, new, or proprietary. The valid scientific evidence shows that each of Novex's claims is false.

10. It is therefore no surprise that Novex has openly flaunted basic FDA legal and regulatory requirements and good practices. Novex has never informed the FDA of its numerous



claims. Despite claiming that the product is a “revolutionary new compound,” Novex has not filed a new dietary ingredient notification with the FDA. Nor has Novex ever made a “General Recognized As Safe” submission.

11. Novex’s blatantly false and misleading claims have not only harmed consumers across the country, but they have harmed ChromaDex and other law abiding and science-based supplement companies as well.

12. These counterclaims seek to put an end to Novex’s unlawful and harmful conduct.

### **JURISDICTION AND VENUE**

13. This is an action for false advertising arising under the Lanham Act, 15 U.S.C. § 1051 *et seq.*; California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code § 17200 *et seq.*; and California’s False Advertising Law, Cal. Bus. & Prof. Code § 17500 *et seq.*

14. This Court has jurisdiction over Lanham Act claim pursuant to 15 U.S.C. § 1121, and 28 U.S.C. §§ 1331 and 1338(b). This Court has jurisdiction over the California state law claims pursuant to 28 U.S.C. § 1367.

15. This Court has general personal jurisdiction over Novex Biotech because its principal place of business is in this District.

16. Venue is proper in this District under 28 U.S.C. §§ 1391(b)(1) and (b)(2) because Novex Biotech is located in this District.

### **THE PARTIES**

17. Plaintiff ChromaDex, Inc. is a corporation existing under the laws of the State of California with its principal place of business at 10005 Muirlands Blvd., Suite G, Irvine, California.

18. Defendant Novex Biotech, LLC is a Utah limited liability company with a principal place of business in Salt Lake City, Utah.

### **GENERAL ALLEGATIONS**

#### **I. ChromaDex Is A Leading Dietary Supplement Company That Helps Consumers Live Healthier Lives**

19. Founded in 1999, ChromaDex began as a fine-chemicals and analytical-testing company that conducted contaminant testing, raw-material testing, and finished-product testing on dietary supplement and drug ingredients. The company's mission was to give consumers confidence that the products they were purchasing contained precisely what they promised. Through its skill, experience, and scientific rigor, ChromaDex quickly became recognized as the gold standard for measuring the safety and quality of dietary-supplement ingredients.

20. Over time, ChromaDex expanded beyond testing products for others and built its own research and development division to develop novel dietary-supplement ingredients. ChromaDex has devoted the same expertise and scientific rigor that it used in its analytical-testing business to this research and development.

21. ChromaDex's research and development has been successful. ChromaDex now sells a number of bulk ingredients for use in consumer products. It also sells products directly to consumers.

22. ChromaDex has a particular focus on developing products that help improve the way people age. The company's flagship products NIAGEN and TRU NIAGEN are leading products in this category.<sup>3</sup>

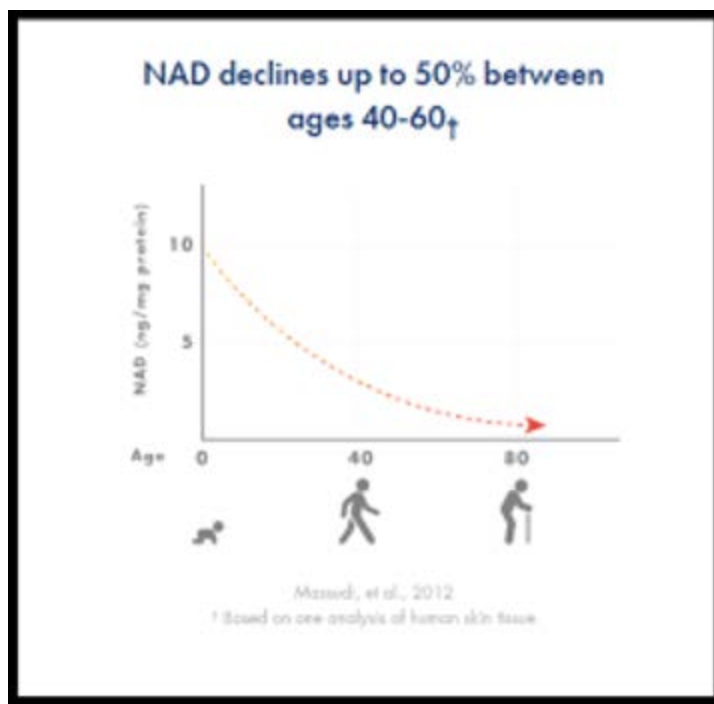
**II. Scientific Evidence Shows that NIAGEN Provides A Number Of Important Health Benefits**

23. ChromaDex's NIAGEN began with research into the vital cellular resource known as NAD, which is found in every living cell in the body. NAD turns food into energy through cellular metabolism, and is crucial to cellular life. NAD is one of the basic building blocks of every human cell. Sufficient levels of NAD are important for healthy aging.

24. But NAD levels naturally decline as humans age. Increased stress and poor diet cause further decreases in NAD. Evidence shows that NAD levels decline by more than 50% from young adulthood to middle age, and continue to decline as humans grow older. When NAD levels drop, the body's cells do not function well and cells can die. Low NAD or NAD-deficiency is associated with many health-related problems of aging (e.g., Alzheimer's, hypertension, obesity, diabetes, and more). The following figure shows how NAD changes during aging.

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<sup>3</sup> For simplicity, this Counterclaim sometimes refers to NIAGEN and TRU NIAGEN collectively as "NIAGEN."



25. To help address decreased NAD levels associated with aging, ChromaDex developed NIAGEN, which contains nicotinamide riboside. Nicotinamide riboside is a potent and bioavailable pre-cursor to NAD. While nicotinamide riboside has been studied for decades, there was a breakthrough in 2004, when scientist Dr. Charles Brenner demonstrated that nicotinamide riboside is converted to NAD within living cells and extends the lifespan of these cells.

26. Since 2011, ChromaDex has committed itself to building on Dr. Brenner's research to further understand how nicotinamide riboside works and how it could be produced and sold as a dietary supplement to increase NAD in humans.

27. After years of research and development, in 2013 ChromaDex developed the first sustainable and reliable way to produce nicotinamide riboside and began selling NIAGEN.

NIAGEN is a patented, proprietary dietary ingredient. In June 2016, ChromaDex launched TRU NIAGEN, its first dietary supplement for direct sale to consumers.

28. NIAGEN and TRU NIAGEN have been extensively studied and proven to be safe and effective. To make sure it is always at the very cutting edge of this scientific development, ChromaDex supports many of the world's leading research institutions and scientists who are working to understand the full potential of NAD and its impact on human health.

29. ChromaDex currently has over 140 partnerships with leading universities and research institutions around the world including the National Institutes of Health, Cornell, Dartmouth, Harvard, Scripps Research Institute, and the Mayo Clinic.

30. The scientific support for nicotinamide riboside, NIAGEN and TRU NIAGEN is voluminous. There are more than 100 studies published about nicotinamide riboside on PubMed, a leading medical and scientific database.<sup>4</sup> ChromaDex has also completed four

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<sup>4</sup> See, e.g., Belenky, P., Bogan, K. L. & Brenner, C. NAD<sup>+</sup> metabolism in health and disease. *Trends in Biochemical Sciences* **32**, 12-19, doi:10.1016/j.tibs.2006.11.006 (2007);

Verdin, E. NAD<sup>+</sup> in aging, metabolism, and neurodegeneration. *Science* **350**, 1208-1213 (2105);

Mouchiroud, L. *et al.* The NAD(+)/Sirtuin Pathway Modulates Longevity through Activation of Mitochondrial UPR and FOXO Signaling. *Cell* **154**, 430-441, doi:10.1016/j.cell.2013.06.016 (2013);

Trammell, S. A. *et al.* Nicotinamide Riboside Opposes Type 2 Diabetes and Neuropathy in Mice. *Scientific Reports* **6**, 26933, doi:10.1038/srep26933 (2016);

Diguet, N. *et al.* Nicotinamide Riboside Preserves Cardiac Function in a Mouse Model of Dilated Cardiomyopathy. *Circulation* **137**, 2256-2273, doi:10.1161/CIRCULATIONAHA.116.026099 (2018);

Vaur, P. *et al.* Nicotinamide riboside, a form of vitamin B3, protects against excitotoxicity-induced axonal degeneration. *FASEB J* **31**, 5440-5452, doi:10.1096/fj.201700221RR (2017);

Rammell, S. A. *et al.* Nicotinamide riboside is uniquely and orally bioavailable in mice and humans. *Nat Commun* **7**, 12948, doi:10.1038/ncomms12948 (2016);

human trials on NIAGEN. *See e.g.*, Trammell, S.A., et al., Nicotinamide riboside is uniquely and orally bioavailable in mice and humans. *Nat Commun*, 2016. 7: p. 12948. Most recently, an eight-week randomized, double-blind, placebo-controlled, human clinical trial that is currently being peer reviewed for publication affirmed that consumption of nicotinamide riboside significantly increased whole blood NAD and other NAD metabolites within two weeks.

31. More than 16 human clinical trials of NIAGEN are registered on [clinicaltrials.gov](https://clinicaltrials.gov), which will further examine the efficacy of nicotinamide riboside. In total, there are currently over 140 pre-clinical and clinical studies either in progress or completed on nicotinamide riboside.

32. These scientific studies have been conducted by the world's leading scientific and medical institutions, including the NIH Institute of Aging, Harvard Medical School, Massachusetts Institute of Technology, The University of Cambridge, Mayo Clinic, University of California at Davis, and Washington University in St. Louis.

33. ChromaDex's research and development work is supervised by ChromaDex's Scientific Advisory Board, whose members hold positions at leading medical institutions, such

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Ear, P. H. *et al.* Maternal Nicotinamide Riboside Enhances Postpartum Weight Loss, Juvenile Offspring Development, and Neurogenesis of Adult Offspring. *Cell Rep* **26**, 969-983 e964, doi:10.1016/j.celrep.2019.01.007 (2019);

Conze, D. B., Crespo-Barreto, J. & Kruger, C. L. Safety assessment of nicotinamide riboside, a form of vitamin B3. *Hum Exp Toxicol*, doi:10.1177/0960327115626254 (2016);

Airhart, S. E. *et al.* An open-label, non-randomized study of the pharmacokinetics of the nutritional supplement nicotinamide riboside (NR) and its effects on blood NAD<sup>+</sup> levels in healthy volunteers. *PLoS One* **12**, e0186459, doi:10.1371/journal.pone.0186459 (2017);

Dolopikou, C. F. *et al.* Acute nicotinamide riboside supplementation improves redox homeostasis and exercise performance in old individuals: a double-blind cross-over study. *European Journal of Nutrition*, doi:10.1007/s00394-019-01919-4 (2019).

as Stanford University Medical School, Harvard Medical School, and Massachusetts General Hospital.

### **III. NIAGEN Complies With FDA's Rigorous Requirements**

34. ChromaDex's products are also safe and comply with the FDA's regulatory requirements.

35. ChromaDex has provided the FDA with the technical and manufacturing details of NIAGEN, defined its purity, impurities, residual solvents, and contaminants, and established the safety of the ingredient. The FDA's acceptance of ChromaDex's notifications recognized that NIAGEN is safe and that ChromaDex had defined the identity of, and manufacturing process for, commercial nicotinamide riboside in accordance with FDA standards and regulations.

36. NIAGEN was also subject to a comprehensive toxicology program that included genotoxicity and mutagenicity studies, acute toxicity, a 14-day dose range finding study, sub-chronic toxicity, and a human study. These studies were conducted in accordance with good laboratory practices as well as preclinical studies following accepted protocols.

37. Moreover, ChromaDex employs an ongoing, comprehensive quality-assurance program that ensures all of its commercially available NIAGEN conforms to its specifications. This assures consumers and regulators alike that all NIAGEN sold in commerce is safe for consumption.

38. Furthermore, NIAGEN was also found to be "Generally Recognized As Safe" (*i.e.*, it has achieved "GRAS" status) for food use by independent experts in the field and ChromaDex submitted a comprehensive GRAS report to FDA. The FDA provided ChromaDex

with a “GRAS No Objection” letter for NIAGEN in August 2016. NIAGEN is therefore safe in vitamin waters, protein shakes, nutrition bars, gum, chews, and powdered beverages, according to the expert panel and as successfully notified to FDA.

39. ChromaDex has also submitted a notification letter to the FDA to inform the agency of its structure/function claims for its dietary supplement products. These letters are required so that the FDA has an opportunity to review and object to any claim that it finds to be improper or unlawful.

#### **IV. ChromaDex Makes Scientifically Valid And Responsible Claims**

40. All of ChromaDex’s marketing claims go through a careful vetting and review process before they are made public. Company experts review each claim to ensure that the claims are scientifically valid and substantiated with competent and reliable scientific evidence. No claim is made unless the scientific team affirms that the claim is proper.

41. NIAGEN is sold nationwide and ChromaDex has customers in all 50 states.

#### **V. Novex Biotech Sells An Inferior Product Known As Oxydrene Elite**

42. Novex markets a product called Oxydrene Elite through multiple online sources including its own website (<https://www.novexbiotech.com/oxydrene.html>), Amazon.com, Walmart.com, vitaminshoppe.com, bodybuilding.com, supplementwarehouse.com, luckyvitamin.com, and facebook.com. On information and belief, Novex also advertises and sells Oxydrene through print advertisements and in retail stores. Novex sells Oxydrene in all 50 states, including California.

43. An image of the Oxydrene package is shown below.





44. Novex claims that this product contains a “revolutionary new compound” and “proprietary formula” that it calls “Crenulin-RCC2.” The product claims to contain the following ingredients:

<b>Supplement Facts</b>		
Serving Size: 2 Capsules		
Servings Per Container: 60		
	Amount Per Serving	% Daily Value
Thiamin (Vitamin B1)	2.5 mg	167%
Riboflavin (Vitamin B2)	2 mg	118%
Niacin	30 mg	150%
Vitamin B6 (as Pyridoxine HCl)	10 mg	500%
Pantothenic Acid (as Calcium Pantothenate)	8 mg	80%
<b>Crenulin-RCC2<sup>®</sup></b>		
<b>A Proprietary Blend Containing:</b>	255 mg	
<i>Rhodiola rosea</i> (root) Extract		†
<i>Cordyceps sinensis</i> Powder		†
Coenzyme Q10		†
<i>Schisandra chinensis</i> (fruit) Extract		†
Eleuthero (root) Extract		†
L-Arginine Alpha-Ketoglutarate 2:1		†
<i>Ginkgo biloba</i> (leaf) Extract		†

† Daily Value not established.

**Other Ingredients:** Rice Flour, Gelatin, Magnesium Stearate, Silicon Dioxide, Titanium Dioxide, FD&C Blue 1.

**A. Novex Promises That Its Oxydrene Will Provide A Number Of Health and Exercise Benefits**

45. Novex widely advertises its products online and through print ads, including through advertisements directed at customers in California. Novex promises consumers that they will obtain a number of health benefits if they take the product. As seen in the image above and throughout its marketing materials, Novex promises that Oxydrene will:

- “increase endurance”
- “improve aerobic power”
- “increase VO<sub>2</sub> Max”
- “improve physical performance”
- “increase oxygen transport to active muscle tissue”
- give you the ability to “push yourself to the next level to see gains unlike anything you have ever achieved before”
- “maximize Aerobic Power and Performance During Exercise”
- “optimize Muscle Recuperation Cycle”
- achieve “faster race times”
- “decrease perception of efforts”

46. As seen in the image below, Novex claims that Oxydrene can “maximize the effects of your exercise regimen” and “increase endurance.”



**Utilize  
Oxydrene® Elite  
as a pre-workout  
supplement in  
order to maximize  
the effects of your  
exercise regimen!**

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.  
© 2017 Novex Biotech. All Rights Reserved.

47. In fact as shown in the advertisement below, Novex goes as far as promising that consumers will actually run faster after taking Oxydrene. It claims that subjects “not only cut 24 seconds off their 6-mile timed-trial ride, but rated the workout as feeling significantly easier after they consumed the extract.”

48. Oxydrene does not state that these results are merely possible, but rather promises that the results are “clinically validated” and “clinically proven” in a “double-blind placebo controlled clinical trial.” Each of these claims were made to consumers around the country, including those in California.

**B. Novex’s Claims For Oxydrene Are False And Misleading**

49. Novex’s claims for Oxydrene Elite are false and misleading. They deceive consumers for a number of reasons.

**i. Oxydrene Is Not Revolutionary, New, Or Proprietary**

50. While Novex claims that “Crenulin-RCC2” is “revolutionary” “new” and “proprietary,” it is in reality comprised entirely of garden variety commodity ingredients that have been on the market for years. There is nothing new, revolutionary, or proprietary about it.

51. The name “Crenulin-RCC2” is nothing more than a scientific-sounding list of letters and numbers that deceives and misleads consumers into thinking the product contains some special ingredient or process, not just ginkgo biloba extract and rhodiola rosea.

52. Upon information and belief, Novex must be aware that its product is not new or “proprietary” because it has never submitted a new dietary ingredient notification to the FDA for approval.

**ii. Oxydrene Does Not Provide The Promised Benefits**

53. Oxydrene also fails to provide any of the health benefits that Novex promises. There is no scientific substantiation for Novex’s claims. To the contrary, the available scientific evidence shows that the ingredients in Oxydrene, whether by themselves or in combination, do not provide the promised health benefits. The claims are simply false.

54. The ingredients in Oxydrene do not and cannot make people “run faster.” Nor do they “increase endurance,” “maximize aerobic power,” “improve physical performance” or “optimize muscle recuperation cycle.” Even if the ingredients could provide some exercise benefits, the dose in the product is entirely too low to see any meaningful benefit.

55. There is no scientific evidence to support Novex’s claims. In fact, the “science” section of Novex’s website exclusively discusses research regarding one of its other products and does not include any studies or discussion of Oxydrene.

**iii. Oxydrene’s Claims Are Not Clinically Validated Through A Human Clinical Trial**

56. Finally, Novex’s claim that its product is “clinically validated” through a “double-blind, placebo-controlled clinical trial” is false. A search of published literature for “Crenulin-RCC2” or a search for a blend of the ingredients listed on the supplement facts for Oxydrene Elite revealed no studies at all, let alone scientific studies that back its sweeping claims of efficacy. Upon information and belief there is no scientifically valid human clinical trial on Oxydrene that supports its claims.

57. Indeed, one supplement watchdog group recently reviewed Oxydrene Elite and concluded that the “cons” of the product included “misleading advertising which quotes a clinical trial that does not seem to exist.”<sup>5</sup>

58. Consumers that purchase Oxydrene, including those in California, never achieve the promised benefits.

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<sup>5</sup> Tony Mason, Muscle Watchdog, Home>Reviews>Oxydrene Elite (Mar. 6, 2019), <https://www.musclewatchdog.com/oxydrene-elite/>

**C. Oxydrene Fails To Follow FDA Requirements**

59. In light of the false and unsubstantiated claims that Novex makes for Oxydrene, it is no surprise that Novex also fails to meet basic FDA requirements for its products.

60. First, despite prominently claiming on its labels and in marketing that Oxydrene or Crenulin-RCC2 is “proprietary” and “new,” Novex has not filed a new dietary ingredient notification under 21 U.S.C. § 350b(a)(2).

61. Second, Novex has not submitted, and upon information and belief, does not have a GRAS submission for Oxydrene or “Crenulin-RCC2”.

62. Third, Novex has not submitted the required 30-day notification letters to the FDA to inform the FDA of the claims it intended to make for the product, as it is required to do under 21 U.S.C. § 343(r)(6)(C).

63. On information and belief, Novex has skirted these regulatory requirements because it recognized that if it informed the FDA of what it is doing, the FDA would take action to put an end to Novex’s misconduct.

**VI. Novex’s Sale Of Oxydrene Harms Consumers And ChromaDex**

64. On information and belief, many consumers have purchased Oxydrene in reliance on Novex’s claims about efficacy, including in California and around the country. On information and belief, based on Novex’s claims, consumers expect they will be able to run faster, have increased endurance, have greater oxygen consumption, and have faster muscle recovery. Yet the product fails to perform as advertised. It provides none of these benefits. Customers have suffered financial harm.

65. If Novex and ChromaDex compete—as alleged by Novex—Novex’s false claims have harmed ChromaDex in the marketplace, in an amount to be proven at trial. Indeed, by bringing this lawsuit, Novex has asserted that NIAGEN competes with Oxydrene and that the products are comparable. These allegations further harm ChromaDex because NIAGEN and Oxydrene are not even remotely comparable products.

66. Any consumer who has purchased or will purchase Oxydrene based on its false marketing statements and incorrect comparisons to NIAGEN is a lost customer for ChromaDex. ChromaDex is harmed by Novex’s distortion in the marketplace.

67. Unfortunately, this is not the first time Novex and its sister companies have brought this type of lawsuit to harass others. Unable to stand on its products and compete in the marketplace, Novex and its sister companies have systematically used litigation as part of their business strategy.

## **CAUSES OF ACTION**

### **COUNT I: FEDERAL FALSE ADVERTISING**

(Violation of Section 43(a)(1) of the Lanham Act, 15 U.S.C. § 1125(a)(1))

68. ChromaDex repeats, re-alleges, and incorporates by reference the allegations contained in paragraphs 1 through 67 as though fully alleged herein.

69. The Lanham Act, 15 U.S.C. § 1125(a)(1)(B), prohibits the use in commercial advertising or promotions of “any word, term, name, symbol or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact” that “misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities.” The Lanham Act also authorizes

“any person who believes that he or she is or is likely to be damaged by” such a violation to file a civil action for an injunction and compensatory damages.

70. Novex has violated the Lanham Act by falsely and deceptively advertising its Oxydrene Elite Product in commercial advertising and promotion. Novex’s claims that Oxydrene provides substantial health benefits including claims that it will “maximize” athletic and aerobic performance, “Optimize Muscle Recuperation Cycle”, and “Increase VO2 Max Through Optimized Systematic Oxygen Utilization,” among others, and that its purported benefits have been “clinically proven.” These claims are false and misleading. The scientific evidence shows that the product has none of those benefits.

71. Novex’s claims that “Crenuline-RCC2” is “proprietary,” “unique”, “revolutionary”, or “new” are false and misleading because it is nothing more than long available commodity ingredients.

72. Novex’s claim that its benefits are “clinically proven” and “clinically valid” is false and misleading. Upon information and belief there is no valid human clinical trial supporting its outlandish claims.

73. Novex has misrepresented the nature, characteristics, and qualities of its goods in commercial advertising and promotion in violation of Section 43(a)(1) of the Lanham Act, 15 U.S.C. § 1125(a)(1).

74. On information and belief, Novex’s violations have been knowing, deliberate, willful, and in bad faith.

75. Novex’s advertising claims are material to consumers. Novex’s false and misleading advertising claims are reasonably relied on by consumers when they purchase



Oxydrene Elite. Novex knows that consumers rely on Oxydrene Elite's advertising claims and intends that they do so.

76. Novex's false and misleading statements have been made in interstate commerce, including in California and over the internet.

77. ChromaDex has been damaged by Novex's conduct in an amount to be proven at trial.

78. ChromaDex's injuries will continue unless injunctive relief is granted.

ChromaDex is entitled to injunctive relief pursuant to 15 USC § 1116 and to recover damages pursuant to 15 U.S.C. § 1117.

## **COUNT II: CALIFORNIA UNFAIR COMPETITION LAW**

(Violation of California's UCL, Cal. Bus. & Prof. Code § 17200 *et seq.*)

79. ChromaDex repeats, re-alleges, and incorporates by reference the allegations contained in paragraphs 1 through 78 as though fully alleged herein.

80. California's Unfair Competition Law prohibits "unlawful, unfair, or fraudulent" conduct in business activities.

81. Novex's has violated and continues to violate California's Unfair Competition Law by making materially false and misleading representations regarding Oxydrene Elite, including that the product is "proprietary," "unique," "revolutionary," or "new" and numerous false claims of "maximized" athletic and aerobic performance, "Optimize Muscle Recuperation Cycle," "Increase VO2 Max Through Optimized Systematic Oxygen Utilization" among others and that its purported benefits have been "clinically proven."

82. Novex's conduct is unlawful as it violates federal and state law, including the Lanham Act, and California False Advertising Law, as well as federal regulations.

83. Novex's conduct constitutes an unfair trade practice because its advertisements and claims about Oxydrene Elite are false and misleading as described above. Novex's conduct is immoral, unethical, oppressive, unscrupulous and substantially injurious to consumers.

84. Novex's advertising claims are material to consumers. Novex's false and misleading advertising claims are relied on by consumers when they purchase Oxydrene Elite. Novex both knows consumers rely on Oxydrene Elite's advertising claims and intends that they do so.

85. On information and belief, Novex's violations have been knowing, deliberate, willful, and in bad faith.

86. ChromaDex has been damaged by Novex's conduct in an amount to be proven at trial. Novex's false and misleading advertising claims put ChromaDex at a competitive disadvantage in the dietary supplement market.

87. ChromaDex's injuries will continue unless injunctive relief is granted. ChromaDex has no adequate remedy at law for these injuries.

### **COUNT III: CALIFORNIA FALSE ADVERTISING LAW**

(Violation of California's UCL, Cal. Bus. & Prof. Code § 17500 *et seq.*)

88. ChromaDex repeats, re-alleges, and incorporates by reference the allegations contained in paragraphs 1 through 87 as though fully alleged herein.

89. Novex's advertising for Oxydrene Elite that claims the product, in particular, "Crenulin-RCC2" is "unique," "revolutionary," "proprietary," or "new" are false, untrue and misleading to consumers. These statements are likely to deceive consumers and the public.

90. Novex's advertising claims also makes false and misleading statements about the purported benefits that Oxydrene Elite provides including numerous false claims of "maximized" athletic and aerobic performance, "Optimize Muscle Recuperation Cycle," "Increase VO2 Max Through Optimized Systematic Oxygen Utilization" among others and that its purported benefits have been "clinically proven."

91. Novex's claim that its benefits are "clinically proven" and "clinically valid" is similarly false and misleading. Upon information and belief there is no valid human clinical trial supporting its outlandish claims.

92. Novex makes each of these claims widely in advertising, including in California and other states.

93. On information and belief, Novex's violations have been knowing, deliberate, willful, and in bad faith.

94. Novex knows or should know that its advertising claims are untrue and misleading to consumers.

95. ChromaDex has been damaged by Novex's conduct in an amount to be proven at trial.

96. ChromaDex's injuries will continue unless injunctive relief is granted. ChromaDex has no adequate remedy at law for these injuries.

**PRAYER FOR RELIEF**

97. ChromaDex respectfully requests that this Court:
- a. Award compensatory damages for lost sales and damage to reputation;
  - b. Award trebled and/or punitive damages for Novex Biotech's misconduct;
  - c. Award costs, attorney fees, and pre- and post-judgment interest;
  - d. Issue an injunction enjoining Novex Biotech's false and misleading advertising and claims, and
  - e. Enter any other relief that is just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment to the United States Constitution, ChromaDex demands a trial by jury on all issues properly triable by jury.

Dated: May 24, 2019

Respectfully submitted,

By: /s/ David L. Mortensen

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 24, 2019, a true and correct copy of the foregoing

**CHROMADEX INC.'S ANSWER AND COUNTERCLAIMS AGAINST NOVEX BIOTECH  
LLC DEMAND FOR A JURY TRIAL** was served on the following via CM/ECF notice:

Jason M. Kerr  
Christopher B. Sullivan  
Alan Dunaway  
Price Parkinson & Kerr  
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*/s/ Rose Gledhill*

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