### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

CHROMADEX, INC., a California corporation, :

Plaintiff,

vs. Civil Action No. 17-8239

ELYSIUM HEALTH, INC., a Delaware

corporation,

Defendant.

#### **COMPLAINT**

Plaintiff ChromaDex, Inc. ("Plaintiff" or "ChromaDex") complains and alleges against Elysium Health, Inc. ("Elysium") as follows for harm caused to ChromaDex as well as New Yorkers at large, who have been willfully deceived and whose health has been placed at risk as a result of Elysium's deceptive and fraudulent business practices.

#### INTRODUCTION

- 1. This case is brought to (a) protect unsuspecting consumers from taking Elysium's "anti-aging" dietary supplement pills, which Elysium deceptively and falsely markets as safe, effective, and based on years of comprehensive FDA regulatory research and testing and (b) to recover damages for the harm suffered by ChromaDex as a result of Elysium's willful and predatory conduct. Elysium's behavior, such as misrepresenting to consumers that Elysium's blue ribbon Nobel Laureate-populated Scientific Advisory Board endorses the safety of the Basis product, evidences Elysium's unscrupulous and unethical elevation of profit over consumers' safety and health.
- 2. Elysium's many misrepresentations, material omissions, and deceptions about its sole product, "Basis," include:
  - Basis is safe because it is made from ingredients that enjoy the approval and blessing of the United States Food & Drug Administration ("FDA") through both a New Ingredient

- Notification Notice ("NDIN") and status as "Generally Recognized as Safe" (or "GRAS"), when those assertions are false.
- Basis is safe because it is "pure," when instead it is "adulterated" as defined by FDA regulations.
- Basis is "pure" because it is white, when in fact the authentic active ingredients are brown.
- Basis is safe because its safety and regulatory profile have been evaluated, tested, and approved by over twenty-one scientists including seven Nobel Laureates on Elysium's Scientific Advisory Board, although none of those scientists have actually comprehensively tested the product's safety and may have been completely unaware that Basis includes detectable levels of the residual solvent Toluene, which is toxic to humans and is ordinarily found in paint thinners and finger nail polish.
- Basis is safe because of the implied endorsements by Harvard University, the University
  of Oxford, and the University of Cambridge, and by famed Nobel Prize winning scientists
  whose roles, at least as far as the science goes, are perfunctory at most and who are merely
  on Elysium's payroll.
- Basis is safe and legitimate because of scientific "Reports and Articles" like George Church's TEDMED talk, Jeff Koons and Eric Kandel's Talk on Art and Empathy and Nobel Laureate Jack Szostak's talk From Telomeres to the Origins of Life.
- Basis is safe because clinical trials establish an accepted safety profile, when in reality
  Elysium has neither conducted nor finished any long-term clinical trials with the
  ingredients currently used by Elysium.
- Basis is safe because it was invented by Dr. Leonard Guarente, who in fact did not invent
   any of the active ingredients in Basis, and whose past scientific publications were
   withdrawn, retracted, and/or "mega-corrected" in disgrace among the scientific
   community.
- Elysium has played a primary role in the science underlying the active ingredients in Basis, when it has not.

- 3. Elysium engages in egregious false advertising and unfair competition clearly intended to deceive and mislead consumers into believing that Basis is somehow approved or otherwise authorized by the FDA when it is not. Elysium fails to disclose to consumers that its Basis product is "adulterated" product as that term of art is defined by the FDA. Elysium tells consumers that Basis is the result of established "science," when, on information and belief, Elysium now uses unknown and unqualified sources of raw ingredients that have not been subjected to rigorous scientific testing for health and safety. Elysium tells consumers that its product is "pure," safe, and healthy, when it is not. Further, Elysium's misrepresentations are willful and intentional, because Elysium knows that the actual ingredients in Elysium's current formulation of Basis have not been approved or endorsed by any governmental agency, and on information and belief, Elysium's alleged "science" underlying the current formulation of the Basis is non-existent. In truth, the only clinical trials conducted with Basis were conducted with authentic ingredients previously supplied by ChromaDex, which are no longer available to Elysium further deceives consumers by hiding from them that Basis contains the Elysium. dangerous solvent Toluene, chronic exposure to which can cause neuro-generative and cognitive dysfunction.
- 4. ChromaDex has been the industry leader in science, research, and development of nicotinamide riboside chloride ("NR") as an ingredient in dietary supplements, and has supplied ingredients to dozens of customers without, prior to this dispute, ever having engaged in litigation against any of them. Elysium is primarily an Internet-based marketing company, with slick materials and big promises but no substance; and in contrast to ChromaDex, is one-for-one when it comes to engaging in customer/supplier litigation. After losing its supply of ingredients from ChromaDex for non-payment, Elysium substituted unknown ingredients, but still represents to the public that its product is bestowed with the regulatory approval and certification of safety afforded by ChromaDex's authentic ingredients. The truth is that Elysium has no regulatory approvals or certifications for its new formulation, but deceives consumers into believing otherwise. Indeed,

most of Elysium's website and marketing materials are dedicated to that lie, followed by a "Purchase Here" button, preying on the frailties and hopes of unsuspecting purchasers.

5. Elysium's pattern of behavior with respect to ChromaDex reflects a nefariously conceived plan to damage and/or steal ChromaDex's NR, reputation, employees, goodwill, and stature in the industry, as well as its customer opportunities. Elysium's marketing falsely "borrows" ChromaDex's research and regulatory achievements to endorse Elysium's new product, and Elysium has maliciously targeted ChromaDex, its employees, and its commercial relationships by disseminating falsehoods about ChromaDex and refusing to pay for large orders – all with the intent of undermining ChromaDex's viability and ability to compete. On information and belief, Elysium falsely disseminated untrue information to investors about ChromaDex's financial health to further interfere with ChromaDex's ability to raise money and defend itself against Elysium's multi-front litigation and deceptive advertising war. And, on further information and belief, Elysium and/or its agents are associated with or responsible for stock "short attacks" intended to drive the share value of ChromaDex down, making it a more accessible take-over target. A company like Elysium does not engage in a concerted unscrupulous and orchestrated plan of this nature, to deceive consumers and harm a competitor, without the authorization and direction of both its management and its board of directors.

#### THE PARTIES

- 6. ChromaDex is a California Corporation with its principal place of business located at 10005 Muirlands Blvd, Suite G, Irvine, California 92618. ChromaDex discovers, acquires, develops, and commercializes patented and proprietary ingredient technologies in the dietary supplement, food, beverage, skin care, and pharmaceutical markets, and is the exclusive licensee of various patent portfolios on ingredient technologies included in its NIAGEN®, TRU NIAGEN™, PTEROPURE®, PURENERGY®, IMMULINA®, and ANTHORIGIN® products.
- 7. Elysium is a Delaware Corporation with its principal place of business located at 594 Broadway, Suite 707, New York, New York 10012. Elysium misleadingly identifies itself as

a company that utilizes science and technology to create consumer health products targeted at slowing and combating the effects of aging, but for reasons described below, it relies on wildly deceptive sleights of hand to create an illusion of health and safety where none exists.

#### **JURISDICTION AND VENUE**

- 8. This is an action for false advertising and unfair competition arising under Lanham Act, 15 U.S.C. § 1125(a) and New York state statutes. Gen. Bus. L. §§ 349, 350.
- 9. This Court has original jurisdiction over federal unfair competition and false advertising claims pursuant to 28 U.S.C. §§ 1331, 1338 and 15 U.S.C. § 1121 (a).
- 10. Supplemental jurisdiction is proper for the state law claims under 28 U.S.C. § 1367(a) because those claims are so related to the federal claims that they form part of the same case or controversy under Article III of the United States Constitution.
- 11. Diversity jurisdiction is also conferred upon this Court by 28 U.S.C. § 1332 because the matter in controversy exceeds the sum or value of seventy-five thousand U.S. Dollars (\$75,000), exclusive of interest and costs, and involves a Delaware Corporation with its principal place of business in New York and a California Corporation with its principal place of business in California.
- 12. Venue is proper in the United States District Court for the Southern District of New York under 28 U.S.C. § 1391(b) because: (1) Defendants' tortious conduct has occurred in this district; (2) Defendants' conduct regular and systematic business in this district; and, (3) a substantial part of the events or omissions giving rise to the claim occurred in this district.

#### **FACTUAL ALLEGATIONS**

#### **ChromaDex is the Industry Leader in Quality and Safety of Supplement Products**

13. Founded in 1999, ChromaDex is a publicly traded natural products company that leverages its complementary business units to acquire, develop, and commercialize patented and proprietary ingredient technologies that address the dietary supplement, food, beverage, skin care, and pharmaceutical markets. In addition to ChromaDex's proprietary ingredient technologies segment, ChromaDex also has a core standards and contract services segment, which focuses on

natural product fine chemicals (known as "phytochemicals") and chemistry and analytical testing services, as well as regulatory consulting. ChromaDex was quickly recognized as the expert in this space, and became the "gold standard" for safety and quality of dietary supplement products. As a result of its relationships with leading universities and research institutions, ChromaDex is able to license early stage, intellectual property-backed ingredient technologies for commercial development. Its proprietary ingredient portfolio is backed with clinical and scientific research, as well as extensive intellectual property protection

#### ChromaDex is the Industry Leader in NR Research and Development

- 14. ChromaDex first became aware of nicotinamide riboside in 2006 based on the work of Dr. Charles Brenner, who was then at Dartmouth University. In 2004, Dr. Brenner demonstrated nicotinamide riboside to be a vital precursor of nicotinamide adenine dinucleotide (NAD), a key vitamin B3 metabolite with important anti-aging effects, which is made available by nicotinamide riboside kinases (Nrks) that are common to yeast, animals, and humans. In 2007, Dr. Brenner's lab discovered a second pathway by which nicotinamide riboside R is converted to NAD and showed that nicotinamide riboside can extend the lifespan of yeast cells by virtue of elevating NAD levels and increasing the activity of NAD-dependent enzymes.
- 15. NAD is responsible for transforming food into energy in essence, metabolic activity. NAD levels decrease with age, and its increased presence (i.e., through consumption of a dietary supplement) is thought to delay certain effects associated with the aging process.
- 16. ChromaDex worked tirelessly to build on research by experts like Dr. Brenner, licensing patents relating to nicotinamide riboside's uses and production from other renowned institutions such as Dartmouth, Cornell, Scripps, and Washington University. Based on its significant efforts and investment, ChromaDex developed the first sustainable way to reliably produce NR for testing, observation and, eventually, human consumption as a dietary supplement. NIAGEN® has been shown to safely and effectively increase NAD+ in human subjects, supported by published research in the October 2016 issue of *Nature Communications*. Since 2013,

ChromaDex has executed over 120 "Material Transfer Agreements" (contracts that govern the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes), all relating to studying the safety and efficacy of NR. Many of these studies have been published in highly prestigious, peer-reviewed scientific journals, such as *Nature*, *Science*, and *Cell Metabolism*.

17. Elysium, by contrast, has not conducted thorough safety studies of the effects of its newly-sourced Basis product, including any actual human studies, and it does not hold any issued patent rights pertaining to NR.

#### ChromaDex's NIAGEN® and TRU NIAGENTM Products

18. Historically, ChromaDex has been a fine chemicals and analytical testing company. Drawing from its extensive expertise and experience in that space, ChromaDex built a research and development arm capable of creating novel ingredients, and has developed and currently sells bulk ingredients to dietary supplement, food, beverage, skin care, and pharmaceutical companies to use in their consumer products. Among other products, ChromaDex sells "NIAGEN®", an ingredient comprised of NR. ChromaDex launched NIAGEN® in May 2013, marking the first time NR was ever commercially available at a scale allowing production of consumer products. Prior to ChromaDex's launch of NIAGEN®, it was difficult to source even small quantities of NR – and even those were prohibitively expensive. Accordingly, NIAGEN® attracted great interest from universities and research institutes seeking to study this unique compound.



19. In addition, in June of 2016 ChromaDex, through its predecessor-in-interest<sup>1</sup>, launched TRU NIAGEN<sup>TM</sup>, its first supplement product for sale directly to consumers. TRU NIAGEN<sup>TM</sup> is comprised of NR in the form of ChromaDex's NIAGEN® product, plus the inactive ingredients microcrystalline cellulose and cellulose, sold together in a vegetarian capsule. TRU NIAGEN<sup>TM</sup> directly competes with Elysium's Basis product. Unlike Elysium's Basis product, TRU NIAGEN<sup>TM</sup> does not contain detectable levels of Toluene.

<sup>&</sup>lt;sup>1</sup> TRU NIAGEN<sup>TM</sup> was launched by ProHealthSpan, which ChromaDex acquired in March 2017.



20. As a result of their high quality, safety, and effectiveness, ChromaDex's NIAGEN® and TRU NIAGEN™ products have been well-received in the marketplace, and their success is directly attributable to ChromaDex's unmatched research, science and testing relating to the development and production of NR.

# <u>ChromaDex's NIAGEN® and TRU NIAGEN™ Products Meet Rigorous Requirements</u> Imposed by the FDA

- 21. ChromaDex consistently performs the maximum safety and toxicology studies on its products, all of which are manufactured in accordance with current good manufacturing practices (or "cGMP") prescribed by the FDA. The company has invested millions of dollars in obtaining these certifications and designations.
- 22. The Federal Food, Drug, and Cosmetic Act and Dietary Supplement Health Education Act requires that manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" notify the FDA about these ingredients. ChromaDex makes NIAGEN® under a New Dietary Ingredient Notification ("NDIN 882") on file with the FDA.
- 23. NDIN 882 discloses the technical and manufacturing details of NIAGEN® and defines its purity, impurities, residual solvents, and contaminants. The FDA accepted NDIN 882

on November 3, 2015, which recognized that ChromaDex had defined the identity of, and manufacturing process for, commercial NR in accordance with the FDA's standards. **Exhibit A.** NIAGEN® is the only NR ingredient in the marketplace with an NDIN.

- 24. NIAGEN® conforms to NDIN 882 and was subject to a comprehensive toxicology program that included Geno toxicity and mutagenicity studies, acute toxicity, a 14-day dose range finding study, sub-chronic toxicity, and a human study. **Exhibit B**. These studies were conducted in accordance with good laboratory practices ("GLP") as well as preclinical studies following accepted protocols.
- 25. In addition to initial safety tests, ChromaDex employs an ongoing, comprehensive quality assurance program that ensures all of its commercially available NR conforms to the specifications as defined in NDIN 882, thereby assuring consumers and regulators alike that all NIAGEN® sold in commerce is safe for consumption.
- 26. Furthermore, NIAGEN® has been "Generally Recognized As Safe" also known as "GRAS" after ChromaDex submitted it to a panel of independent experts in toxicology. The FDA provided ChromaDex with a "GRAS No Objection" letter for NIAGEN® in August 2016. **Exhibit C**.
- 27. ChromaDex's TRU NIAGEN<sup>TM</sup> product is also manufactured in accordance with NDIN 882 and has the benefit of the GRAS designation as a result of the fact that NIAGEN® is the only active ingredient in TRU NIAGEN<sup>TM2</sup>. Elysium's Basis product, which directly competes with TRU NIAGEN<sup>TM</sup>, does not have an NDIN covering it nor has it, or any of its current ingredients, *ever* been designated as GRAS.
- 28. While ChromaDex has for over 11 years diligently researched and developed the technology to produce and confirm the safety of NR, Elysium was founded in 2014 and began selling in 2015. Elysium was only able to go to market so quickly by wrongfully riding on the coattails of ChromaDex's research and investment in NR. On information and belief, Elysium

<sup>&</sup>lt;sup>2</sup> NDIN 882 relates to 180 milligrams of NIAGEN®. TRU NIAGEN™ is 250 milligrams.

was founded with the specific goal of wresting control of NR from ChromaDex through unscrupulous means, rather than to compete honestly or fairly. In fact, Elysium's co-founder Dr. Leonard Guarente told ChromaDex Board Member Rob Fried in 2015 that it was their intention to purchase ChromaDex, presumably to obviate the need for a supplier relationship. It speaks volumes that, while ChromaDex has enjoyed successful business relationships with hundreds of customers, Elysium has tried to cannibalize its only supplier by stealing its employees, deliberately refusing to pay for goods, and suing ChromaDex three times in a relationship only three years old, as described further below.

#### Elysium Conspired to Unjustly Wrest Control of the NR Market from ChromaDex

- 29. The only two active ingredients in Elysium's Basis product are NR (250 mg) and Pterostilbene (50 mg), both of which were previously sold to Elysium by ChromaDex. *See* Exhibit **D**. The "supplement facts" panel on Elysium's Basis bottles direct consumers to take two capsules per day. *Id*. Other ingredients in Basis are said to be microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica.
- 30. For years, ChromaDex was Elysium's sole supplier of NR. ChromaDex supplied Elysium with its NIAGEN® ingredient, as well as with pTeroPure, a separate proprietary health ingredient comprised of Pterostilbene, which is an antioxidant found in blueberries.
- 31. ChromaDex generally sells its products in combinations like the combination previously sold to Elysium. Elysium, however, desired to be the only client of ChromaDex's eligible to purchase this particular combination of NR and Pterostilbene, despite its knowledge that ChromaDex at the time sold that same combination to at least two other customers. To secure this arrangement, Elysium offered ChromaDex minimum purchases in exchange for exclusivity.
- 32. On June 30, 2016, Elysium offered to purchase an amount well over its minimum requirements, totaling approximately \$2.95 million in orders. The *day* after ChromaDex completed its obligation under those orders (August 10, 2016), Elysium falsely accused ChromaDex of violating the exclusivity provision of the parties' purchase agreement and refused

to pay ChromaDex the \$2.95 million balance for the orders it placed on June 30 and *had already received*. On information and belief, Mark Morris, the then-Vice President of Sales at ChromaDex, and who was responsible for managing the overall ChromaDex relationship with Elysium as well as negotiating this specific transaction with Elysium and others, orchestrated this refusal as an agent of Elysium.

- 33. Mr. Morris gave notice that he was resigning from ChromaDex on July 16, 2016 two weeks after Elysium placed the extraordinarily large June 30<sup>th</sup> order, and less than four weeks *before* Elysium refused to pay the balance. Upon his departure, Mr. Morris claimed not to know where he was going or what he would be doing next. That was apparently a lie, since he immediately thereafter became employed by Elysium and records establish his travel to Elysium.
- 34. ChromaDex was soon faced with an additional serious challenge.. In June 2016, the same month of Mr. Morris's abrupt departure to Elysium, a shortseller published an online article containing false and misleading information about the Company. This article included disparaging allegations, among others, about certain ChromaDex shareholders and suggested that the Company was engaged in misconduct. In response, ChromaDex promptly issued a press release refuting the false and misleading statements in the shortseller's attack, after which the shortseller agreed to retract the article and issued a public apology to the Company. Curiously, over a year after the retraction, Elysium has rehashed some of the accusations from the shortseller's now-retracted article in a complaint filed in the Southern District of New York. Elysium does not explain how these "allegations" are at all relevant to its purported claims (they are not) and, thus, they appear to be little more than an attempt to further malign the Company.
- 35. ChromaDex's Director of Scientific Affairs, Mr. Ryan Dellinger, also resigned *effectively immediately* on August 10, 2016, the *same day* Elysium refused payment, and immediately became employed by Elysium.
- 36. Both Mr. Morris and Mr. Dellinger immediately accepted positions at Elysium upon departing ChromaDex and are still employed there to this day.

- 37. The "transitions" of Messrs. Morris and Dellinger from ChromaDex to Elysium shed light on a 2015 conversation between Mr. Rob Fried, a ChromaDex board member, and Elysium's Chief Scientific Officer, Dr. Leonard Guarente, who told Mr. Fried that Elysium's intention was to buy ChromaDex, not partner with it. What better way to buy a perceived threat than steal its employees while refusing to pay millions of dollars for goods already received? As a public company, Elysium was able to monitor ChromaDex's finances and calculate just how to create a shortfall that would threaten ChromaDex's continued ability to do business, including to buy raw supplies necessary to manufacture new NR for which other customers would actually pay. Ultimately, Elysium attempted to isolate ChromaDex from its other customers and then orchestrate the downfall of the deal that it demanded ChromaDex make, all in an effort to undermine and weaken ChromaDex.
- 38. On information and belief, Messrs. Morris and Dellinger conspired and acted in concert with Elysium to corner the market on NR and then "ripcord" the supply from ChromaDex such that it could not sell NIAGEN® to other parties or recover from a nearly \$3 million loss.

# Elysium Flaunts FDA Regulations and General Safety Considerations with its Current Basis Product

39. After Elysium refused to pay for the raw ingredients that it ordered in June and received from ChromaDex in July 2016, ChromaDex repeatedly sought to engage Elysium in amicable discussions to resolve the matter. Elysium, however, steadfastly refused to pay for the product or to make any good faith efforts to resolve the matter. After numerous unsuccessful attempts toward a resolution, ChromaDex had no choice but to notify Elysium in November 2016 that it would not renew the supply agreement. That agreement expired in early 2017 (after a sixmonth notice period required by the applicable agreement). After ChromaDex stopped supplying Elysium with NR and pTeroPure, Elysium procured a new alternative source of NR and Pterostilbene from unknown suppliers, which it now uses to make Basis. The contents of these ingredients do not come from ChromaDex or its authorized supplier in the United States and are less than "pure".

- 40. Unlike ChromaDex, on information and belief, Elysium has not invested the very significant resources required to perform safety, toxicology, and human clinical studies on its Basis product to satisfy the regulatory requirements imposed by the FDA to obtain NDI and GRAS status. On further information and belief, (a) neither Basis nor any of its current ingredients have *ever been submitted* for either GRAS status or an NDIN, and (b) the sources of the new ingredients in Basis have not been identified and/or adequately safety-tested. Elysium's conduct and omissions demonstrate that it prioritizes profits above its consumers' desires and needs to be accurately informed about the true contents of the Basis product.
- 41. The inclusion of newly-sourced NR in Elysium's Basis product means that the supplement contains a new dietary ingredient as defined by 21 U.S.C. § 350(b). And, because Elysium has failed to submit a NDI notification for the new ingredient, the current Basis product is considered by the FDA to be "adulterated" under 21 U.S.C. § 342(f)(1)(B), despite Elysium's claims of safety and purity made to induce consumers to purchase Basis.
- 42. In fact, Basis is far from "safe." Since switching from the use of ChromaDex ingredients to a wholly unregulated version of the ingredients, Elysium's Basis product is now contaminated with the toxin Toluene. According to the Centers for Disease Control and Prevention ("CDC"), Toluene is an industrial solvent present in paint thinners, finger nail polish, lacquers, and adhesives, exposure to which are known to cause cognitive impairment, nervous system malfunctions, vision and hearing loss, retardation, immune, kidney, liver, and reproductive maladies. **Exhibit E**. The FDA has not approved the use of Toluene as a residual solvent in food and dietary supplements. 21 C.F.R. Part 137, Subpart C. As such, Elysium's Basis product is unsafe for human consumption.

# Elysium Makes False Statements, Omits Material Facts, and Fabricates its Role in the Science of NR (Which ChromaDex Largely Developed) to Sell its Basis Product

43. To promote, pump, and increase sales of Basis (and cut into sales of ChromaDex's directly competing TRU NIAGEN<sup>TM</sup> supplement), Elysium routinely publishes misleading information in an effort to deceive consumers about the purported safety and purity of Basis.

Elysium's false and deceptive statements take a variety of forms and are propagated through multiple channels, but the end goal is consistent: to increase sales of Basis by deceiving and confusing consumers into falsely believing that Basis has been approved by the FDA, is generally safer than it is, and that it is "pure."

- 44. Elysium also relies on smoke and mirror marketing to create the wholly inaccurate impression that Elysium itself played a significant role in the scientific research concerning NR, and that its current Basis product is both novel and well-researched, when in fact it is not. Elysium is, however, aware that ChromaDex and scientists with whom it worked (e.g., Dr. Brenner) were the driving force behind the development of science relating to NR not Elysium's founders or paid scientific advisory board endorsers and that only ChromaDex's NIAGEN® product has been clinically proven to raise NAD+ levels. **Exhibit F**.
- 45. Yet Elysium touts in a banner ad: "Meet Basis. The only supplement clinically proven to raise NAD+ levels." Elysium falsely refers to Basis as "the world's first cellular health product informed by genomics," when in fact ChromaDex's long-standing, well-researched products (including specifically the NIAGEN® and pTeroPure it sold to Elysium) came first, and Elysium boldly even directly links to *ChromaDex's* studies to support *Elysium's* claims. **Exhibit** G. These false and misleading claims deceptively convey to consumers that Basis has been better researched than it has, assuming it has at all, and constitute outright falsehoods concerning Elysium's participation in relevant research.
- 46. In an interview with *Allure* magazine, published on October 18, 2017, one of Elysium's founders, Dr. Guarente states: "With regard to Basis, the pill seems simple, but the amount of science behind it is quite extensive." **Exhibit H**.
- 47. Guarente further states that the science surrounding NR "began almost 30 years ago." These statements are calculated to lead consumers to falsely believe that Dr. Guarente and Elysium are the originators and primary contributors to this body of research, when indeed the very history he references relates to *ChromaDex's* research which does not apply to Elysium's current Basis product, given the "mystery ingredients" that now comprise Basis.

### Elysium Misleads Consumers Into Mistakenly Believing that the FDA Has Somehow Approved or Endorsed its Basis Product When it Has Not

- 48. Perhaps the most egregiously deceptive and correspondingly effective aspect of Elysium's disinformation campaign is its repeated references to the FDA in its marketing materials, despite the fact that the FDA has never recognized Basis as GRAS and none of the ingredients in Basis are covered by an NDIN. By weaving references to the FDA throughout its multi-faceted sales pitch for Basis, Elysium deceptively leads consumers to mistakenly believe that the federal government agency responsible for the oversight of supplements has given its blessing to Basis, when nothing could be further from reality.
- 49. For example, Elysium represents to the public that "the ingredients in Basis have been tested for safety and are produced in facilities that meet FDA requirements. Basis also undergoes rigorous third party purity testing." **Exhibit I**. Elysium's repeated references to the FDA are carefully crafted to deceive consumers into believing that Elysium's supplements meet governmental standards designed to protect them. In fact, Elysium's reference to the agency's standards only fosters the incorrect notion that the Basis product has undergone rigorous levels of regulatory scrutiny.
- 50. Elysium makes similar statements on its *Endpoints* blog site. As an initial matter, the blog is formatted like a magazine, a clear attempt to obfuscate Elysium's identity as the author of the content thereon and the source of the science allegedly supporting Basis's safety. According to a June 6, 2017 *Endpoints* post: "If a supplement maker introduces a new ingredient to the market it's supposed to notify the FDA." **Exhibit J**. Without citation, Elysium further states: "[w]hen DSHEA (Dietary Supplement Health and Education Act of 1994) was passed . . . there were roughly 4,000 products on the market; today there are more than 77,000, so needless to say there have also been many new ingredients introduced as well. Part of the reason the FDA issued its latest guidance in 2016, by its own admission, is that compliance with the NDI notification process has been inconsistent. The FDA hopes to get more notifications of NDIs submitted, thereby avoiding companies simply introducing new and potentially unsafe ingredients into the

consumer market." *Id.* Yet while informing consumers on a blog site designed to market Basis that a "supplement maker is supposed to notify the FDA of a new ingredient" by furnishing the agency with an NDI, *id.*, Elysium itself has not done so for its current product.

- 51. In the "Our Approach" and "How We're Different" sections of Elysium's website, Elysium claims that "during the course of manufacturing Basis there are a total of five quality and purity audits before a batch is shipped. All manufacturing facilities are located in the US and are compliant with the cGMP [Current Good Manufacturing Practices] regulations as stipulated by the FDA." **Exhibit K**. Not only do these statements mislead consumers into believing that the FDA has somehow approved of Basis or its ingredients, they are, on information and belief, false.
- 52. On information and belief, the foregoing statements could only be true when Elysium sourced NR and Pterostilbene *from ChromaDex*, and even then those statements could only be based on *ChromaDex's* extensive testing and compliance with cGMP regulations because Elysium has not conducted its own testing or complied with cGMP regulations. Elysium relied exclusively on ChromaDex's research and testing during the time when ChromaDex supplied NR and Pterostilbene to Elysium, but ChromaDex's research, testing, and validation processes simply do not apply to Elysium's current product comprised of its "mystery ingredients".
- 53. Elysium further misrepresents its Research & Development process by falsely telling consumers that it complies with the FDA New Dietary Ingredient ("NDI") requirements and "safety" and "efficacy" testing: "We conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of 'new dietary ingredients." **Exhibit K**, *supra*. This representation, again, is false.

#### **Elysium Lies to Consumers About Clinical Trials for its Current Basis Product**

54. Elysium further misrepresents to the public that it has conducted or is conducting Phase 1 and Phase 2 clinical trials on the Basis product, stating that Elysium's Research & Development process includes both "(1) Safety Testing: Typically characterized as a 'Phase 1

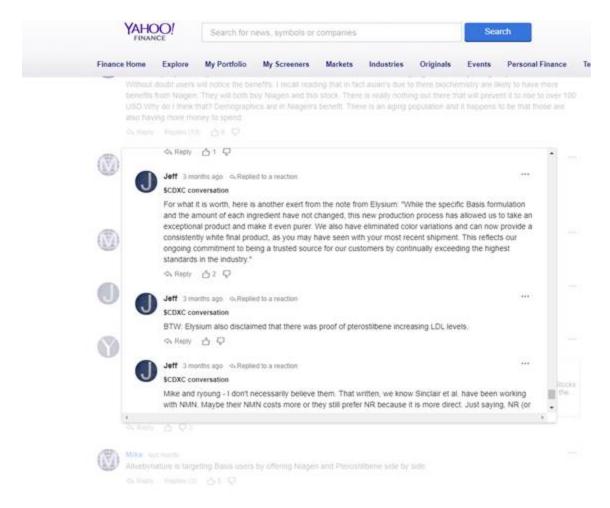
clinical trial, this stage determines the safety and pharmacokinetics of the compound in healthy individuals" and (2) "Efficacy Testing: Typically characterized as a 'Phase 2' clinical trial, this human study looks at safety and efficacy of a given molecule." **Exhibit K**, *supra*. Elysium goes on to proclaim: "Results from our First Clinical Trial: In our first clinical trial participants who took the recommended dose of Basis saw their NAD+ levels increase 40% and remain at that level for the duration of the trial." *Id*. On information and belief, the only clinical trials conducted on NR and pTeroPure were those conducted by ChromaDex, using ChromaDex's active ingredients, rather than the adulterated ingredients currently included in Elysium's Basis product.

- 55. On December 6, 2016, Elysium issued a public press release "announcing Topline Clinical Trial Results for its First Product Basis." **Exhibit L.** However, to the extent any such study was completed, Elysium was at that time purchasing and using its supply of NR from ChromaDex. Elysium also announced that "its first human clinical trial designed to evaluate the safety and efficacy of its first product, Basis<sup>TM</sup>, met its primary and secondary endpoints. The study, which was placebo-controlled, randomized, and double-blinded, evaluated the safety and efficacy of Basis<sup>TM</sup> [nicotinamide riboside (NR) and Pterostilbene] in 120 healthy participants ages 60-80 over an eight-week period. Participants received either the recommended dose (250 mg NR and 50 mg Pterostilbene), double the recommended dose or a placebo daily for the eight-week trial. The study found that participants experienced no serious adverse events and confirmed that Basis<sup>TM</sup> is safe for daily use as determined by standard safety measures. The study also showed that in participants taking the recommended dose of Basis, TM NAD+ levels increased from baseline in whole blood by an average of 40% at four weeks and maintained that increase for the duration of the trial. Participants taking double the recommended daily dose saw their NAD+ levels increase approximately 90% at four weeks, and a significantly higher level of NAD+ (compared to the recommended dose of Basis<sup>TM</sup>) was maintained for the duration of the trial." *Id.* (emphases added).
- 56. Elysium's own chief scientist, Dr. Guarente, admits the referenced study cannot be theirs. In a *Fast Company* article profiling Elysium, the writer notes: "The issue is that the clinical

trials involved in doing this can take more than a decade, and even then that is no guarantee a drug will be approved." **Exhibit M**. On that topic, Dr. Guarente states: "If there's a benefit that can be had now, then I think it doesn't make sense to wait a decade or more until some derivative [from a drug company] becomes available—though I'm not saying that's not a good thing to do too' says Guarente." *Id*. Unlike ChromaDex, Elysium – having been founded in 2014 – has not performed over a decade of research, including a human clinical study, to justifiably call their product safe and induce consumers to purchase the supplement on that basis. Elysium is perpetuating a fraud on consumers.

#### **Elysium Falsely Claims That Basis is "Pure"**

57. Elysium even goes so far as to try and convince consumers that its Basis product, by virtue of being white in color, is purportedly "pure." In a recent post on the Yahoo financial board, one consumer reported that Elysium made such statements in response to an inquiry about Basis; *see*:



#### Exhibit N.

58. Basis cannot be considered "pure." In its normal state, NR is brown and thus the Basis product was brown when it incorporated ChromaDex's NIAGEN® ingredient. Now that Elysium includes mystery NR in Basis, the product is "white" in color, which Elysium disingenuously relies upon to market the product as "pure." In reality, the Basis product is only white because it lacks an authentic version of a key ingredient.

### Elysium Hides Its Lack of Factual "Basis" for Safety Claims by Touting Ties with Highly Credentialed but Uninvolved Scientists, including Founder Dr. Leonard Guarente

59. Elysium was co-founded by Dr. Leonard Guarente, Elysium's Chief Scientist and lead "scientific" spokesman. Guarente recognizes himself as an "expert" in aging science, but his scientific research methods are suspect at best. Of the three papers Guarente has published on anti-aging, remarkably two have been retracted and another has been subjected to a "mega-

correction" as characterized by research watchdog Retraction Watch. **Exhibit O.** It is highly unusual in any scientific career that a single paper is retracted, but beyond experience that a scientific expert has had his only three papers on the subject attacked and undermined to the point of requiring "mega-corrections" and full retraction.

- 60. On information and belief, Guarente is closely involved in the operations of Elysium and its willful and malicious dissemination of deliberately misleading and patently false advertising promoting Basis as safe and pure when both he and the company know Elysium has not conducted any research to support such claims. Guarente's spotty history as an unscrupulous researcher and his involvement in continually covering up Elysium's fraudulent scheme discredit any claims he makes about Basis or relevant science.
- 61. Elysium also confuses consumers about the safety and testing of Basis by inferring that its blue ribbon panel of Nobel Laureates serving as Elysium's "Scientific Advisory Board" have all been involved in the science and discovery behind the Basis product, and implying that those members vouch for the safety of the product. In marketing materials for Basis, Elysium tells consumers "Our board guides the scientific direction of Elysium. Its members are leaders in science and technology, pioneering a better approach to health." Exhibit P. Such members include Dr. Aaron Ciechanover from the Cancer Biology department at Technion Israel Institute of Technology, Dr. Eric Kandel, from Columbia University, Dr. Jack Szostak, from Harvard University, Dr. Martin Karplus from Harvard University, Sir Richard Roberts from New England Biolabs, Dr. Thomas Südhof from Stanford University and Dr. Paul Modrich from Duke University School of Medicine. *Id.* Elysium further stamps the seal of approval on Basis by referencing other luminary members of its Scientific Advisory Board, including Dr. Martin Blaser of New York University, Dr. George Church from Harvard University, Dr. Ana Maria Cuervo of Einstein College of Medicine, Daniel Fabricant formerly of the FDA, Dr. Mark Gerstein of Yale University, Dr. Richard Granstein of Weill Cornell Medical College, Dr. Lee Hood of the Institute for Systems Biology, Dr. Stuart Kim of Stanford University, Dr. Jim Kirkland of the Mayo Clinic, Dr. Bruce McEwen of The Rockefeller University, Dr. David Moore of Baylor College of

Medicine, Dr. Dariush Mozaffarian of Tufts University, Bijan Salehiazdeh of NuviMed Capital and Dr. Eric Schadt of the Icahn School of Medicine. *Id.* In fact, Elysium's webpage includes smiling pictures, reports, and links to articles by some of these scientists, including Dr. Jeff Koons, Dr. Eric Kandel, and Dr. Jack Szostak, regarding topics like Nobel Prize winning medical research on telomeres and George Church's TEDMED talk about genome mapping. *Id.* 

- Nobel Laureates, and at least twenty-one scientific luminaries is a bald attempt to convince consumers to accept Elysium's claims of safety wholesale. *None* of these individuals are identified as having participated in any actual research, development or testing of the Basis product, *id.*, and, on information and belief, not *one* has publicly made any statement endorsing or validating the safety or any other characteristic of Basis, yet their prominence on Elysium's website clearly implies their endorsement of the company and its products as safe for human consumption. In fact, the website listing these individuals is accompanied by a prominently located and displayed "BUY NOW" button, encouraging customers to purchase Basis immediately after learning that these renowned medical researchers and doctors are on Elysium's board. *Id.* Upon information and belief, the identified scientists have *not* all endorsed Basis or vouched for its safety, and all of these scientists are paid fees and compensation for their services to Elysium. In reality, they are being paid for their implied endorsement of the safety of Basis, despite the absence of data supporting such an endorsement.
- 63. Elysium further deceives its consumers by also including client testimonials emphasizing their reliance on the alleged scientific foundation of Basis, and their comfort level afforded by Elysium's bevy of apparent sponsors from medical and scientific fields.
- 64. Elysium's website clearly demonstrates that Elysium wants customers to draw these conclusions and make purchasing decisions based on them. For example, Pamela Olin, who is described as an "annual subscriber" for a supply of Basis, is quoted as saying: "I like the fact that Elysium has scientists on staff. I like the fact that there is data . . . It just seemed like two simple ingredients. The fact that there are so many knowledgeable people involved in this, and

that you were so responsive when I had questions. It left me feeling secure in the knowledge that I was given and made it worth a shot. I'm thoroughly enjoying it." **Exhibit Q** (emphases added).

- 65. Another customer, Suzy Oo, is quoted as saying: "I was following Dr. Guarente's work actually. Scientists have their groupies—I guess I was one of his. He's kind of a rockstar in the scientific community . . . I went through the original research papers. I looked at it as a hypothesis. Based on what's out there, is it likely to work and is it going to cause me any harm? Based on everything I read, I didn't think it was going to cause me any harm and based on the literature I thought Basis made sense." **Exhibit R**.
- 66. As another representative example, another consumer, Tom Flynn, is quoted as saying: "I came across an article about Elysium. I said, let me look at this because of the credibility of the founder and his work at MIT. I was buoyed by the idea that these people had confidence in the research and were proficient in it." **Exhibit S**.
- 67. Not surprisingly, placed below each "testimonial" is a "Subscribe Today" button by which a consumer can purchase annual supplies of Basis, consistent with Elysium's sales pitch to take two pills per day, forever. *See e.g., id.*

#### **Elysium Falsely Implies Product Safety by Associating with Renowned Institutions**

- 68. To further the falsehood that Basis has been tested and approved for consumption, Elysium touts its research collaboration and partnerships with renowned academic institutions, including the following as representative examples:
- the University of Cambridge through a four-year commitment with The Milner Therapeutics Institute addressing aging, cognitive health, metabolic health and general well-being (Exhibit P),
- Harvard University in a three-year commitment with the T.H. Chan School of Public Health addressing cellular function, aging, and gut microbiome (**Exhibit P**); and,
- The University of Oxford, through a three-year commitment with the Oxford Medical Sciences Division, addressing cellular health (**Exhibit P**).

Although none of these renowned institutions appears to have participated in the testing of the Basis product, their prominence on Elysium's website is a clear, implied endorsement of the company and its products as safe for human consumption, which is not the case.

#### **Elysium Fails to Inform Consumers that Basis Contains a Dangerous Toxin**

- 69. Based on concerns over counterfeit and unsafe products, and in the interest of protecting public safety, ChromaDex acquired commercially available, current lots of Basis from multiple sources and had them tested. A series of analyses were performed on eight Elysium Basis product samples received from various, recent sources from July and August 2017. The reports on these tests reveal that the Basis products acquired in August 2017 are contaminated by the industrial solvent Toluene. The presence of a toxic industrial solvent like Toluene in Basis, a product intended for and prescribed for daily human consumption, raises serious public health and safety concerns for New York consumers.
- 70. As noted above, Elysium recommends that its customers take two pills daily. This results in repeated, chronic exposure to Toluene. Although the International Conference on Harmonization (or "ICH") propounds guidelines that list an "acceptable" level of "permitted daily exposure" to Toluene as a "Residual Solvent", these guidelines are indications solely for *pharmaceutical* (i.e., prescription-only) drugs taken for specific, often short, durations under the supervision of a doctor. **Exhibit T**. Often, these drugs are utilized to treat more serious conditions, such that exposure to impurities may be considered more tolerable in light of the condition(s)' severity, the limited duration of exposure, and the medical supervision under which they are administered. In addition, pharmaceuticals are required to undergo different testing and are held to a materially different standard than supplement products. Elysium specifically markets Basis as a health supplement to avoid this level of scrutiny from the FDA, and despite its knowledge

of persistent levels of Toluene in Basis – continues to encourage its consumers to take these contaminated pills twice-daily<sup>3</sup>, without any testing specific to Basis proving its safety<sup>4</sup>.

71. In its marketing materials, Elysium omits any reference to these significant facts, which would undoubtedly be material to the purchasing decisions of unsuspecting consumers.

#### **CLAIMS AND CAUSES OF ACTION**

# FIRST CAUSE OF ACTION FALSE ADVERTISING UNDER 15 U.S.C. § 1125(a)

- 72. ChromaDex repeats and re-alleges the allegations contained in paragraphs 1 through 71, above.
- 73. On information and belief, Elysium markets its Basis product as "safe" and "pure" without any product-specific testing to support those claims indeed, it is adulterated and unsafe. Elysium actively seeks to confuse consumers by creating a false impression of safety, purity, and governmental review, including but not limited to by creating implied endorsements by highly-regarded medical professionals and associating with world-class institutions, when in actuality neither of these groups is involved is actively involved in researching, monitoring, or ensuring the safety of the Basis product itself. Elysium further seeks to legitimize its lack of foundational, proven information applicable to its Basis product by peppering the Internet with magazine-style blog posts hosted on third party websites that are really deceptive "infomercials" peddling falsehoods to induce consumers to buy Basis.
- 74. Specifically, Elysium's marketing, advertising and promotional statements and activities are false and misleading misrepresentations of fact and confuse consumers in New York and across the country into believing that its current Basis product (a) is manufactured subject to

<sup>&</sup>lt;sup>3</sup> ChromaDex, too, is aware of the ICH Guidelines relating to Toluene and its associated "permitted daily exposure" in pharmaceutical products. Based on that awareness, ChromaDex as a courtesy supplied its pharmaceutical and bulk customers with Certificates of Analysis listing every ingredient (including residual solvents, if any, such as Toluene) as part of ChromaDex's ongoing effort to protect consumer safety. These manufacturers and product companies were therefore able to make informed decisions about how to process ChromaDex-provided ingredients for products intended for human consumption. The responsibility for the safety of those products, however, lies with those customers, including specifically Elysium.

<sup>&</sup>lt;sup>4</sup> By contrast, ChromaDex's ingredients have undergone numerous safety and toxicology tests.

an NDIN, (b) has been approved by the FDA, (c) is the result of extensive scientific research and development conducted by Elysium, (d) has been clinically tested for safety, (e) is manufactured at facilities that meet FDA requirements, and, (f) has been endorsed by a multitude of renowned scientists and academic institutions. None of the foregoing is true, and consumers are likely to rely upon those false, misleading and deceptive statements, all to their detriment and the detriment of ChromaDex and its NIAGEN® and TRU NIAGEN<sup>TM</sup> products.

75. Elysium is therefore engaged in false advertising in violation of 15 U.S.C. § 1125(a), which prohibits a party from "misrepresenting the nature, characteristics, [or] qualities" of a product in "commercial advertising or promotion." Elysium misrepresents the nature, characteristic, and qualities of the Basis supplement in violation of the law, causing ChromaDex and consumers alike irreparable harm for which ChromaDex has no adequate remedy at law.

# SECOND CAUSE OF ACTION FEDERAL UNFAIR COMPETITION 15 U.S.C. § 1125(a)

- 76. ChromaDex repeats and re-alleges the allegations contained in paragraphs 1 through 75, above.
- 77. ChromaDex is the only supplier of NR ingredients and products in the United States with an NDIN filed with the FDA, GRAS status, and clinical trial support related to NR. Although Elysium was not involved in the research and testing of NR, the company touts the safety of its current Basis product based on research conducted by ChromaDex or using ChromaDex's ingredients. In fact, Elysium's current Basis product has not undergone the rigorous testing required to make these statements and thus consumers in New York and across the country are likely to be confused by this information. Elysium even goes so far as to make statements suggesting they are a discovering or pivotal party in the NR field, when they are not.
- 78. On information and belief, Elysium's marketing, promotion, and sale of untested NR-based products as "safe" and "pure" in interstate commerce, in competition against ChromaDex, harms consumers and ChromaDex. Consumers are likely to rely on this information in their purchasing decisions at commercial detriment to ChromaDex.

79. Elysium is therefore engaged in unfair competition in violation of 15 U.S.C. § 1125(a) and has caused ChromaDex irreparable harm for which ChromaDex has no adequate remedy at law.

### THIRD CAUSE OF ACTION DECEPTIVE PRACTICES UNDER NEW YORK GENERAL BUSINESS LAW § 349

- 80. ChromaDex repeats and re-alleges the allegations contained in paragraphs 1 through 79, above.
- 81. By the acts described herein, Elysium has engaged in deceptive acts and practices directed at consumers in the conduct of its business by disseminating misleading information to induce the purchase of a harmful product injuring both New York consumers' financial well-being and personal health and safety, in violation of New York General Business Law § 349(h).
- 82. Elysium's acts alleged herein have caused monetary damages to ChromaDex in an amount to be proven at trial in excess of \$75,000.
- 83. Elysium's acts have caused, and will continue to cause, irreparable injury to ChromaDex and its business and reputation unless and until Elysium is permanently enjoined.

# <u>FOURTH CAUSE OF ACTION</u> DECEPTIVE PRACTICES UNDER NEW YORK GENERAL BUSINESS LAW § 350

- 84. ChromaDex repeats and re-alleges the allegations contained in paragraphs 1 through 83, above.
- 85. By the acts described herein, Elysium has engaged in "false advertising" as defined in and in violation of New York General Business Law § 350-a because Elysium has promoted its products in a misleading manner.
- 86. Elysium's acts alleged herein have caused monetary damages to ChromaDex in an amount to be proven at trial in excess of \$75,000.
- 87. Elysium's acts have caused, and will continue to cause, irreparable injury to ChromaDex and its business, reputation, and trademarks, unless and until Elysium is permanently enjoined.

# FIFTH CAUSE OF ACTION TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

- 88. ChromaDex repeats and re-alleges the allegations contained in paragraphs 1 through 87, above.
- 89. By the acts described herein, Elysium knowingly induced ChromaDex to modify and limit at detriment to ChromaDex its ability to sell NR and pTeroPure in combination to other customers, two of whom ChromaDex was already selling this combination to and of which Elysium was acutely aware. Those economically advantageous relationships were terminated to satisfy Elysium's exclusivity demand, which Elysium demanded in bad faith to damage ChromaDex.
- 90. Knowing that it would never fulfill its obligations under its large purchase order, and in effort to short ChromaDex of money and resources, Elysium intentionally and improperly took action to end those known relationships, as well as ChromaDex's ability to form future and maintain current relationships, all the while planning to "short" the system by ordering a huge supply of NR, accepting that supply, and then refusing to pay for it. Elysium's dissemination of false information directly to investors as well as in the media, after it failed to pay for a final huge order, asserting that ChromaDex was failing damaged additional existing and potential customer relationships.
- 91. ChromaDex has been economically damaged and continues to be economically damaged as a result of Elysium's intentional conduct, including but not limited to in the form of lost revenue, in an amount to be determined at trial.

#### PRAYER FOR RELIEF

#### ChromaDex prays that:

- A. Elysium, its employees, representatives, and agents be enjoined from making false and/or misleading statements about the safety and purity of its Basis (or any other) supplement;
- B. Elysium be ordered to cease and desist from selling its Basis product unless or until the product is compliant with applicable federal and state laws and regulations;

C. Elysium be ordered to publish for a period of not less than twelve months corrective

advertising in all media cogently explaining that is not the subject of a filed NDIN at the FDA;

D. The Court grant any and all relief to which ChromaDex may be entitled pursuant

to the Lanham Act, 15 U.S.C. §§ 1051, et seq., including but not limited to treble damages and

attorneys' fees, in an amount not less than \$200,000,000;

E. The Court grant any and all relief to which ChromaDex may be entitled pursuant

to state law and state common law, including enhanced damages and attorneys' fees;

F. The costs of this action be taxed against Defendant; and,

G. The Court grant ChromaDex such other and further relief as the Court may deem

just and proper.

#### **DEMAND FOR JURY TRIAL**

ChromaDex demands trial before a jury on all issues so triable.

Dated: October 25, 2017 Cooley LLP

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