U.S. FOOD & DRUG ADMINISTRATION

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

February 5, 2019

Pure Nootropics, LLC
Christopher Dziak
10532 Figaro Dr Nw
Albuquerque, NM 87114-3890 US

RE: 565425

Dear Mr. Dziak:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.purenootropics.net in October 2018 and has determined that you take orders there for your products Alpha GPC, Lion's Mane, CDP Choline Capsules, Piracetam,[1] Vitamin D3 5000 IU, Turkey Tail Mushroom Powder, and Ginkgo Biloba Capsules. The claims on your website establish that the products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Examples of some of the claims observed on your website that provide evidence your products are intended for use as drugs include the following:

On the page of your website titled "Alpha GPC 50% Capsules & Powder":

- "Helpful in reducing symptoms of cognitive decline…(prescribed in Europe to Alzheimer's patients)"
- "[Alpha GPC 50%] not only supports memory formation and learning, but prevents cognitive decline (such as senile dementia and Alzheimer's disease)."

On the page of your website titled "Lion's Mane Mushroom Powder & Capsules":

[1] We note that your Piracetam product is not labeled as a dietary supplement. Therefore, this letter does not address the issue of whether products containing piracetam can be lawfully marketed as dietary supplements.

- "Great for brain injury recovery"
- "Reduce symptoms of anxiety & depression"

On the page of your website titled "Citicoline for Enhanced Cognition":

- "Citicoline or Cytidine 5'diphosphocholine (CDP-Choline) . . . was originally developed in Japan for stroke and is now also approved in Europe for use in stroke. *[sic]* Parkinson's disease and other neurological disorders."
- "As a drug, citicoline has been proposed for use in traumatic brain injuries, stroke, vascular dementia, [and] Parkinson's disease … where it has the function of stabilizer of cell membranes and reduces the presence of free radicals. In particular, there is some evidence of a stimulating role of citicoline for the release of dopamine neurotransmitters in the brain."

On the page of your website titled "Piracetam Capsules Subscription":

- "Age Related neuro protection"
- "Protects the brain after injury"
- "Depression/anxiety relief"
- "Prescription drug for Alzheimer's/Parkinson's"
- "Major diseases, such as dementia, schizophrenia, Alzheimer's and Parkinson's, have all been treated using piracetam. Even dyslexia can be improved with piracetam usage."

On the page of your website titled "Vitamin D3 5000 IU Softgels":

- "Reduces incidence of falls and bone breaks in the elderly"
- "Supplementation shown to reduce risk of Alzheimer's Disease"
- "Can reduce risk of influenza …"
- "Research shows supplemental vitamin D can also reduce the risk of cancer, heart disease and multiple sclerosis"

On the page of your website titled "Turkey Tail Mushroom Powder":

- "[H]elping to fight infections, illness and diseases."
- "Antibacterial"

On the page of your website titled "Ginkgo Biloboa Capsules":

- "Most consider the main benefit of Ginkgo biloba to be its ability to prevent the worsening of memory problems due to … neurodegenerative disease."
- "People who suffer from metabolic syndrome, a group of complaints that increase the risk of

diabetes, stroke and heart disease, often take Ginkgo biloba to decrease that risk."

- "[S]upplementing Ginkgo biloba can slow the buildup of plaque deposits and reduce heart attack risk."
- "In persons who have experienced brain injury due to cancer treatment, this supplement helps to strengthen the memory."
- "Kaempferol [a chemical in Ginkgo biloba] is believed to possess the ability to both prevent and fight cancer."
- "Found commonly in onions, it [the flavonoid isorhamnetin in Ginkgo biloba] is thought to ease complications of diabetes and improve heart health."
- "Ginkgolides A, B, and C [chemicals in Ginkgo biloba] help to reduce inflammation by reducing blood clotting and adjusting the dilation of blood vessels."

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products Alpha GPC, Lion's Mane, CDP Choline Capsules, Piracetam, Vitamin D3 5000 IU, and Ginkgo Biloba Capsules are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, Alpha GPC, Lion's Mane, CDP Choline Capsules, Piracetam, Vitamin D3 5000 IU, and Ginkgo Biloba Capsules fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with all requirements of federal law, including FDA regulations.

Unsubstantiated Advertising Claims

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See POM Wonderful LLC v. FTC, 777 F.3d 478, 504-05 (D.C. Cir. 2015); FTC v. Direct Mktg. Concepts, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), aff'd, 624 F.3d 1 (1st Cir. 2010); FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), aff'd, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

With regard to the advertising claims discussed above, please notify Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

FD&C Act Violations

With regard to the FDA-related violations cited above, you should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Shawn Goldman, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,

William A. Correll Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

MARY K. ENGLE

Digitally signed by MARY K. ENGLE
Date: 2019.02.04 12:59:31 -05'00'

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission