UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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DUANE WOMACK, individually and on behalf of all others similarly situated,

Plaintiff,

- against -

EVOL NUTRITION ASSOCIATES, INC., doing business as Red Dawn Energy, a Georgia Corporation,

Defendant.

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CLASS ACTION COMPLAINT

JURY DEMAND

6:21-cv-332 (BKS/TWD)

Plaintiff Duane Womack ("Plaintiff") individually and on behalf of all others similarly situated, based on the investigation of counsel and his own individual knowledge as to Plaintiff's own circumstances, hereby complains against defendant EVOL Nutrition Associates, Inc., doing business as Red Dawn Energy, ("Defendant" or "EVOL") as follows:

PRELIMINARY STATEMENT

1. Defendant manufactures, bottles, markets, distributes, and retails the Sleep Walker (sold in both liquid and capsule forms) and Red Dawn Liquid Products (collectively, the "Products") as dietary supplements that provide extra energy and enhances the consumer's mood. Accordingly, Defendant advertises its Products primarily as an energy drink, competing with coffee and caffeine laden drinks. However, to compete in this market, Defendant formulated the Products contain unapproved and unsafe dietary ingredients, whose risk are not adequately disclosed.

2. Defendant labels the Products as containing a "Proprietary Blend" or "Proprietary Focus/Mood Blend" which includes, among other things, the substance Beta-phenyl-gamma-aminobutyric acid (better known as "Phenibut" or "GABA"). Phenibut is an anti-anxiety medication prescribed in Russia. Phenibut is associated with significant side effects, including dizziness, nausea, poor balance, fatigue, and feelings of electric shocks in the arms and legs. In larger doses, Phenibut can cause trouble breathing and unconsciousness. Simply put, Phenibut is

a dangerous drug that has no place being in any food product.

3. Phenibut has never been approved for use as a dietary ingredient and is not generally recognized as safe by the United States Food and Drug Administration ("FDA"), despite being used in the SleepWalker Energy products. This renders the Products misbranded and adulterated under Federal and State law. Misbranded and adulterated food products cannot legally be manufactured, held, advertised, distributed or sold. Thus, misbranded and adulterated food has no economic value and is worthless as a matter of law, and purchasers of misbranded food are entitled to a full refund of the purchase price.

4. Additionally, Plaintiff and other Class Members suffered from a number of side effects related to the Phenibut, in combination with the other ingredients, in the Products. Plaintiff did not know that the Products contained a dangerous and unapproved ingredient which would have such negative effects. Had Plaintiff and Class Members known the true nature of the Products, they would not have purchased such Products, or would have paid less. As a result of Defendants' misconduct and misrepresentations, Plaintiffs and putative Class Members have suffered injury in fact, including economic damage.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to the Class Action Fairness Act, 28 U.S.C. §§1332(d), 1446, and 1453(b). Plaintiff alleges that he and the Class Members are citizens of different states from Defendant, and the cumulative amount in controversy for Plaintiff and the Class exceeds $5 million, exclusive of interest and costs.

6. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) because many of the acts and transactions giving rise to the violations of law complained of herein occurred in this District, and because Defendant conducts business itself or through agent(s) in this District, by advertising, marketing, and/or distributing the Products in this District; and/or otherwise has sufficient contacts within this District to justify Defendant being fairly brought into Court in this District.

PARTIES

7. Plaintiff Duane Womack is, and at all times relevant hereto was, a resident of Rome, New York and a citizen of New York. Plaintiff Womack has purchased several of Defendant's Sleep Walker products in the past four years, including at a Speedway store located in New York on or about June 2020. Plaintiff Womack purchased Defendant's Sleep Walker products believing it to be a safe, lawful dietary supplement which would provide an energy boost, similar to coffee. After consuming Defendant's Sleep Walker products, Plaintiff's adverse side effects, including dizziness, nausea, or fatigue for over twelve hours. These side effects were so pronounced, that Plaintiff did not finish the remaining Products that he purchased.

8. Defendant EVOL Nutrition Associates, Inc., doing business as Red Dawn Energy, is a Georgia Corporation with its headquarters in Marietta, Georgia. EVOL manufactures nutritional supplements and other energy drinks. EVOL manufactures, markets, advertises, distributes and retails a line of Red Dawn branded supplements, including the Sleep Walker and Red Dawn Products, throughout the United States.

SUBSTANTIVE ALLEGATIONS

9. Defendant formulates the Products as dietary supplements that provides consumers with a boost of energy without the jitters associated with other energy drinks. The Products at issue in the instant lawsuit have since become Evol's best seller. These Products are sold in capsule form, as two ounce (60 ml) liquid single-serving "shots," or in larger four to sixteen ounce multi-serving bottles. The liquid Products are offered in a number of flavors. But regardless of the form the Products take, each of the Products is marketed the same; as a dietary supplement that provides energy, improves mood, and increases focus:

10. Defendant markets these Products as safe and effective, but they are not. Instead of being safe, the Products contain Phenibut, an unapproved drug that is used to treat insomnia, depression, stuttering, vestibular disorders, irregular heartbeat, and post-traumatic stress disorder in Russia, Ukraine, Belarus and Latvia. There is no good scientific evidence, however, to support Phenibut's treatment of these conditions. Instead, Phenibut seems to be used primarily as a recreational drug.

11. Phenibut property works by mimicking the brain chemical called gamma-aminobutyric acid, which is a calming neurotransmitter. When taken orally, Phenibut can cause many side effects, including a hangover-like-effect of dizziness, nausea, poor balance, and fatigue. Phenibut in large doses can cause trouble breathing, feelings of electric shocks in the arms and legs, and unconsciousness. Phenibut can cause dependence when taken regularly and some people develop a dependence on Phenibut after using it only once. Given the dangers associated with

Phenibut, it has no legitimate use in normal consumer products.

12. People who use Phenibut regularly, and then stop taking it, may experience withdrawal symptoms. These symptoms can include decreased appetite, nausea, muscle aches, anxiety, agitation, trouble sleeping, and seizures. Even without dependence, Phenibut's long-term symptoms can include depression and fatigue. Indeed, there is little scientific research to show what is a safe dose of Phenibut for an adult, if any.

13. Nonetheless, Defendant markets, distributes, and retails the Products to consumers without any disclosure of the dangers associated with the Phenibut in the Products or the fact that Phenibut is not approved for use in the United States. As a result of these misrepresentations and omissions to its customers about the safety of the Products, Defendant have taken millions of dollars from unsuspecting consumers.

14. On April 10, 2019, the FDA warned Defendant that Products were misbranded, as they listed Phenibut as a dietary ingredient, which is it is not. But, the FDA is not the only regulatory agency to take action against the use of Phenibut in consumer products. Phenibut has been banned in Hungary, Lithuania, Italy, and Australia, citing concerns due to withdrawal and overdose.

15. In the United States, food and dietary supplement labeling and safety is regulated by a combination of state and federal law. The Federal Food, Drug, and Cosmetic Act (the "FDCA"), enacted in 1938, generally prohibits misbranding of food and any adulterated food products. The FDCA was supplemented by the Dietary Supplement Health and Education Act in 1990 to clarify and to strengthen the FDA's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods.

16. Under sections 201(s) and 409 of the FDCA, any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. Food additives are not subject to premarket approval and are known as "GRAS" or Generally Recognized as Safe.

17. Any unapproved food additive used in a beverage or other conventional food causes the food to be adulterated under section 402(a)(2)(C) of the FDCA (21 U.S.C. 342(a)(2)(C)). Adulterated foods cannot be legally imported or marketed in the United States.

18. However, section 201(s) of the FDCA exempts dietary ingredients used in dietary supplements from the food additive definition. Although a dietary ingredient used in a dietary supplement must not adulterate the supplement under section 402(f) of the FDCA (21 U.S.C. § 342(f)), it does not have to be GRAS for its intended use in the supplement. Nonetheless, other ingredients intended for use in dietary supplements, such as binders, excipients, and fillers, are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, non-dietary ingredients added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for their intended use.

19. Under section 201(ff)(1) of the FDCA (21 U.S.C. § 321(ff)(1)), a dietary ingredient is a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances.

20. The FDA noted, in its April 10, 2019 letter to Defendant, that:

> Phenibut is not a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Because phenibut does not fit in any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring phenibut in your product labeling as a dietary ingredient causes your products to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

Accordingly, because Phenibut is not a dietary ingredient, it is a food additive. Phenibut is not recognized as GRAS and, therefore, it requires premarket approval. Defendant has not sought such approval. The Products are misbranded under federal and New York State law. *See* NY Agri & Mkts L § 201; 21 U.S.C. § 343.

21. Because Defendant's Products have not been approved by the FDA, they are

misbranded and/or adulterated and may not be sold in the United States. But this is not a purely technical violation of food labeling regulation. The purpose of these regulatory requirements is to protect consumers from exposure to newly created dietary supplements which are not demonstrated to be safe and effective. This is the exact situation born out here.

22. There are serious safety issues associated with Defendant's Products. The health problems associated with the unapproved Phenibut in the Products manifest themselves when consumers consume the Products at recommended serving sizes. Plaintiff and other consumers of the Product report feeling unwell after ingesting a single serving. Plaintiff and other consumers of the Products report feeling uneasy, nausea, and other hangover like symptoms for up to twenty-four hours after using the Products.

23. Defendant mislead consumers about the immediate health dangers and risk of addiction caused by Phenibut in the Products. By marketing the Products as an energy drink and thereby comparing the risk to consumption of mild to moderate amounts of caffeine, a universally regarded safe sympathomimetic when used in isolation, reasonable consumers believed the product to be safe. Defendant also failed to adequately warn users of the potential serious dangers of Phenibut, which Defendant knew or should have known might result from consuming the Products.

24. A reasonable consumer would believe that an energy drink, including the Products, would not have unreasonably dangerous or addictive ingredients. The presence of Phenibut renders the Products unreasonably dangerous and addictive, which would be material to a reasonable consumer. Therefore, the omission of warnings regarding such ingredients would be deceptive and misleading to the reasonable consumer.

25. Indeed, both Federal law and New York Law, prohibit marketing unsafe foods and dietary supplements. A food shall be deemed to be adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to health." 21 U.S. Code § 342; NY Agri & Mkts L § 199-A. Here, Phenibut is not only injurious to health, but also addictive. Additionally, the law prohibits any food labeling that is false or misleading in any particular. 21

U.S. Code § 343; NY Agri & Mkts L § 202-A. Defendant's inclusion of Phenibut as a dietary ingredient in the Product is misleading, because Phenibut is not dietary ingredient and is not GRAS. Additionally, Defendant's misrepresentations regarding and failure to warn about the health risks associated with Phenibut is false and misleading.

26. Plaintiff and putative Class Members would not have purchased the Products had they known the Products contained Phenibut, which is harmful and addictive or had they known about Defendant's scheme to sell the Products as misbranded and adulterated dietary supplements. Accordingly, Plaintiff and putative Class Members have been injured.

27. Consumers have suffered and will continue to suffer substantial injury as a result of Defendant's violations of the FDCA, NY Agri & Mkts L §§ 199 and 202, and NY GBL §§ 349 and 350. In addition, Defendant has been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

CLASS ACTION ALLEGATIONS

28. Plaintiff brings this action on behalf of themselves and the following Class pursuant to Federal Rule of Civil Procedure 23(a), (b)(2) and/or (b)(3). Specifically, the Class is defined as:

> All persons in state of New York and who purchased the Sleep Walker (sold in both liquid and capsule forms) and Red Dawn Liquid Products between March 23, 2018 and the present.

Excluded from the Class are (a) any person who purchased the Products for resale and not for personal or household use, (b) any officers, directors or employees, or immediate family members of the officers, directors or employees, of any Defendant or any entity in which a Defendant has a controlling interest, (c) any legal counsel or employee of legal counsel for any Defendant, and (d) the presiding Judge in this lawsuit, as well as the Judge's staff and their immediate family members.

29. Plaintiffs reserve the right to amend the definition of the Class if discovery or further investigation reveals that the Class should be expanded or otherwise modified.

30. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** Class Members are so numerous and geographically dispersed that joinder of all Class Members is impracticable. While the exact number of Class Members remains unknown at this time, upon information and belief, there are thousands, if not hundreds of thousands, of putative Class Members. Class Members may be notified of the pendency of this action by mail and/or electronic mail, which can be supplemented if deemed necessary or appropriate by the Court with published notice.

31. **Predominance of Common Questions of Law and Fact – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** Common questions of law and fact exist as to all Class Members and predominate over any questions affecting only individual Class Members. These common legal and factual questions include, but are not limited to, the following:

a. Whether Defendant's Products are misbranded under the law;

b. Whether Defendant's Products are adulterated under the law;

c. Whether Defendant's marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive;

d. Whether Defendant's acts, omissions or misrepresentations of material facts violate certain state deceptive practice acts, including those of New York;

e. Whether Plaintiff and putative Class Members have suffered an ascertainable loss of monies or property or other value as a result of Defendant's acts, omissions or misrepresentations of material facts;

f. Whether Plaintiffs and putative Class Members are entitled to monetary damages and, if so, the nature of such relief; and

g. Whether Plaintiffs and putative Class Members are entitled to equitable, declaratory or injunctive relief and, if so, the nature of such relief.

Pursuant to Rule 23(b)(2), Defendant has acted or refused to act on grounds generally applicable to the putative Class, thereby making final injunctive or corresponding declaratory relief appropriate with respect to the putative Class as a whole. In particular, Defendant has manufactured, marketed, advertised, distributed and sold Products that are deceptively

misrepresented as safe and legal, when they are not.

32. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiff's claims are typical of the claims of the Members of the Class, as each putative Class Member was subject to the same uniform deceptive misrepresentation or omissions regarding the contents and health risks associated with the Products. Plaintiff shares the aforementioned facts and legal claims or questions with putative Class Members, and Plaintiff and all putative Class Members have been similarly affected by Defendant's common course of conduct alleged herein. Plaintiff and all putative Class Members sustained monetary and economic injuries including, but not limited to, ascertainable loss arising out of Defendant's deceptive misrepresentations regarding the content and benefits of the Products, as alleged herein.

33. **Adequacy – Federal Rule of Civil Procedure 23(a)(4).** Plaintiff will fairly and adequately represent and protect the interests of the putative Class. Plaintiff has retained counsel with substantial experience in handling complex class action litigation, including complex questions that arise in this type of consumer protection litigation. Further, Plaintiff and his counsel are committed to the vigorous prosecution of this action. Plaintiff does not have any conflicts of interest or interests adverse to those of putative Class Members.

34. **Insufficiency of Separate Actions – Federal Rule of Civil Procedure 23(b)(1).** Absent a class action, Class Members will continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual consumers, the resulting multiplicity of lawsuits would cause undue burden and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated consumers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendants. Accordingly, the proposed Class satisfy the requirements of Fed. R. Civ. P. 23(b)(1).

35. **Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2).** Defendant have acted or refused to act on grounds generally applicable to Plaintiff and all Members of the Class, thereby making appropriate final injunctive relief and declaratory relief, as

described below, with respect to Class Members as a whole.

36. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available methods for the fair and efficient adjudication of the present controversy for at least the following reasons: (1) the damages suffered by each individual putative Class Member do not justify the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct; (2) even if individual Class Members had the resources to pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed; and (3) the claims presented in this case predominate over any questions of law or fact affecting individual Class Members.

COUNT I
Violation of The Unfair and Deceptive Trade Practices Act
New York GBL § 349, *et. seq*.
(On behalf of the Class)

37. Plaintiff repeats and realleges the allegations in paragraphs above as if fully set forth herein.

38. Plaintiff brings this cause of action on behalf of himself and the Class against Defendant.

39. Defendant's foregoing acts and practices, including their omissions, were directed at consumers and likely to affect multiple consumers through the marketing, distribution, and retail of the Products within the State of New York.

40. Defendant's foregoing deceptive acts and practices, including their omissions, were material, in part, because they concerned the safety of the dietary supplement and their legality. Defendant omitted material facts regarding the Products by failing to disclose that the Products contain an illegal substance, were unsafe, and addictive. Rather than disclose this information, Defendant marketed the products as a safe dietary supplement.

41. Defendant's foregoing deceptive acts and practices, including their omissions, were and are deceptive acts or practices in violation of New York's General Business Law section 349, Deceptive Acts and Practices, N.Y. Gen. Bus. Law 349, *et. seq.*, in that:

a. Defendant manufactured, labeled, packaged, marketed, advertised, distributed, and sold the Products, when they knew, or should have known, that the Products were unsafe, illegal, and addictive;

b. Defendant knew the concerns regarding safety and legality was unknown to and would not be easily discovered by Plaintiff and Class Members, and would defeat their ordinary, foreseeable and reasonable expectations concerning the performance of the Products; and

c. Plaintiff and Class Members were deceived by Defendant's failure to disclose and could not discover the safety issues and addictive nature of the Products or that the Products could not perform as represented prior to purchasing the Products.

42. Defendant willfully or knowingly violated the Unfair and Deceptive Trade Practices Act. Defendant was aware or could not be unaware of the requirement for FDCA for marketing dietary supplements, the fact that Phenibut was included in the Products, and the fact that Phenibut had a number of health related side effects, but marketed the products anyways. Indeed, even after the FDA 2019 letter, Defendant continued to market the Product with Phenibut.

43. Plaintiff and Class Members suffered damages when they purchased the Products. Defendant's unconscionable, deceptive and/or unfair practices caused actual damages to Plaintiffs and the Class Members who were unaware that the Products were unsafe, illegal, and addictive.

44. Defendant's foregoing deceptive acts and practices, including their omissions, were likely to deceive, and did deceive, consumers acting reasonably under the circumstances. Consumers, including Plaintiff and putative Class Members, would not have purchased their Products had they known about the true nature of the Products.

45. As a direct and proximate result of Defendant's deceptive acts and practices, including their omissions, Plaintiff and Class Members have been damaged as alleged herein, and are entitled to recover actual and statutory damages to the extent permitted by law, including class action rules, in an amount to be proven at trial.

46. In addition, Plaintiff and Class Members seek equitable and injunctive relief against

Defendants on terms that the Court considers reasonable, and reasonable attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated Class Members, prays for relief and judgment, including entry of an order:

A. Declaring that this action is properly maintained as a class action, certifying the proposed Class, appointing Plaintiffs as Class Representatives and appointing Plaintiffs' counsel as Class Counsel;

B. Directing that Defendants bear the costs of any notice sent to the Class;

C. Awarding Plaintiffs and Class Members actual damages, restitution and/or disgorgement;

D. Awarding Plaintiff and Class Members statutory damages, as provided by the applicable state consumer protection statutes invoked above;

E. Enjoining Defendant from continuing to engage in the unlawful and unfair business acts and practices as alleged herein;

F. Awarding Plaintiff and Class Members restitution of the funds that unjustly enriched Defendant at the expense of Plaintiff and Members,;

G. Awarding Plaintiff and Class Members pre- and post-judgment interest;

Awarding attorneys' fees and litigation costs to Plaintiff and Class Members; and

H. Ordering such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

DATED: March 24, 2021

s/Jan M. Smolak

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