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(54) Title: NUTRITIONAL SUPPLEMENTS FOR SLEEP

(57) Abstract: Disclosed herein are nutritional supplements containing one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower, including compositions, formulations, and combinations of ingredients in the phytonutrient nutritional supplement. The disclosed nutritional supplement can include one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower, a gelling agent such as pectin or gelatin, and an oligosaccharide, such as tapioca.

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NUTRITIONAL SUPPLEMENTS FOR SLEEP

TECHNICAL FIELD OF THE INVENTION

[0001] Disclosed herein is a nutritional supplement containing one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower, including compositions, formulations, and combinations of ingredients in the phytonutrient nutritional supplement. The disclosed nutritional supplement can include one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower, a gelling agent such as pectin or gelatin, and an oligosaccharide, such as tapioca.

BACKGROUND TO THE INVENTION

[0002] Sleep disturbances affect a significant portion of the population, leading to various health and productivity issues. While synthetic sleep aids including melatonin and/or alcohol exist, they have undesirable side effects. There is a need for a natural supplement that promotes better sleep with minimal side effects.

[0003] Some botanical extracts are believed to have sedative and anti-anxiety properties and possible alternatives for consumers wishing to avoid traditional sleep products that include melatonin or alcohol. However, the unpleasant smell and taste of valerian root make it difficult for some to consume in traditional forms, such as teas and tinctures. In addition, the high alcohol concentration of traditional botanical tinctures make them inappropriate for some consumers, such as children, immune comprised individuals, and those desiring to avoid consuming alcohol.

[0004] Gummy supplements have grown in popularity, in part, due to their ability to mask the flavor of unpleasant phytonutrients. One major challenge with creating gummy supplements, however, is delivering consistent potency across all batches. Typical processes for creating a phytonutrient ingredient to include in a gummy product includes processing organic botanical matter into a powdered form and using a liquid solvent to extract the active constituents. These processes create challenges with consistency and even distribution of the active constituents.

[0005] Another major challenge is finding the balance between having a high-potency product with a palatable flavor profile. Using a traditional lipid-based extract creates

difficulties with the flavor profile and with manufacturing quality during curing. End products often experience a decreased shelf life due to the separation of the lipids in the final product.

[0006] There is a need to create a nutritional supplement sleep product that does not contain alcohol or melatonin and that addresses the challenges of creating a gummy supplement by using concentrated phytonutrient compounds provided as a water-soluble liquid.

SUMMARY OF THE INVENTION

[0007] The invention described herein provide a nutritional supplement for improving sleep. In some embodiments, the nutritional supplement includes a therapeutically effective amount of two or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower. In some embodiments, the nutritional supplement is free of synthetic sleep aids. In some embodiments, the nutritional supplement is provided in the form of a gummy.

[0008] In some embodiments, the nutritional supplement includes a therapeutically effective amount of three or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower. In some embodiments, the nutritional supplement includes a therapeutically effective amount of valerian root, linden, agua de azahar, and passion flower.

[0009] In some embodiments, the nutritional supplement is free of melatonin. In some embodiments, the nutritional supplement is free of alcohol. In some embodiments, the nutritional supplement is free of cannabis.

[0010] In some embodiments, the nutritional supplement further includes pectin, an oligosaccharide and water. In some embodiments, the oligosaccharide is tapioca.

[0011] In some embodiments, a method of manicuring the nutritional supplements described herein is provided, wherein the method includes extracting the essence of botanical material from two or more of valerian root, linden, agua de azahar, and passion flower in a liquid, concentrating said extracted liquid, and incorporating the liquid concentrate into a gummy. In some embodiments, extracting the essence of botanical material from two or more of valerian root, linden, agua de azahar, and passion flower in a liquid comprises soaking the botanical material in a solvent to allow for the dissolution of soluble compounds. In some

embodiments, the solvent comprises alcohol and water. In some embodiments, the water is oxygenated water. In some embodiments, the water has a pH of about 8 to about 9.5.

[0012] In some embodiments, incorporating the liquid concentrate into a gummy includes preparing a gummy formulation comprising pectin and a liquid concentrate comprising two or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower; boiling off excess liquid from the liquid concentrate to achieve a viscous consistency suitable for mixing; combining the concentrated liquid concentrate with the gummy formulation and mixing to ensure an even distribution throughout the mixture; and pouring the mixture into molds and allowing to cool and set.

[0013] In some embodiments, a method of improving sleep quality or sleep duration is provided, wherein the method includes administering a therapeutically effective amount of the nutritional supplements disclosed herein prior to bedtime, such as 30 minutes, or 1 hour, 2 hours, or 3 hours before bedtime.

DETAILS OF INVENTION

[0014] Embodiments of the invention disclosed herein disclose a nutritional supplement for improving sleep quality and/or duration that does not contain alcohol or melatonin. In some embodiments, the nutritional supplement is provided in the form of a gummy. In some embodiments, the nutritional supplement includes one or more phytonutrient compounds and/or botanical extracts. The invention disclosed herein provides a sleep enhancement supplement comprising a unique combination of botanical extracts that improves sleep quality, reduces sleep onset time, and/or enhances overall sleep duration. In some embodiments, the nutritional supplement includes one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower. In some embodiments, the sleep enhancement supplement comprising a synergistic blend of valerian root, linden, agua de azahar, and/or passion flower provides a natural option for individuals seeking to improve their sleep quality and overall well-being, devoid of significant side effects associated with synthetic sleep aids.

[0015] In some embodiments, a non-cannabis nutritional supplement having a phytocannabinoid profile rich in phytonutrients is provided. For example, in some embodiments, the non-cannabis nutritional supplement contains phytonutrients including, for example, but not limited to, one or more minor cannabinoids and one or more terpenes. In some embodiments, the minor cannabinoid is cannabidiol (CBD). In some embodiments, the

nutritional supplement sleep product is provided in the form of a gummy. In some embodiments, the nutritional supplement includes one or more phytonutrient compounds and/or botanical extracts. In some embodiments, the nutritional supplement includes one or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower.

[0016] Valerian root (*Valeriana officinalis*) is an herb from regions of Europe and Asia. It is believed to have many benefits, including as a treatment for both insomnia and anxiety. Valerian root contains valerenic acid, an active ingredient with sedative effects. Specifically, valerenic acid is thought to act on brain receptors for the chemical (neurotransmitter) gamma-aminobutyric acid (GABA), which calms and slows the brain. Valerian root can have a strong and pungent “musky” or “woody” aroma. The taste of valerian root can be bitter and is often described as similar to black licorice.

[0017] Linden is an herb that comes from various species of *Tilia*, or lime tree. Flowers from 2 linden species (*Tilia cordata* and *Tilia platyphyllos*) have been historically used to soothe nerves and treat health problems associated with anxiety. The flowers were steeped as a tea to relieve anxiety related to indigestion, irregular heartbeat, and vomiting. Today, linden is used in many cough and cold remedies. Active ingredients in linden help promote sweating, which may help treat people with fevers.

[0018] Agua de azahar (orange blossom water) is the distillation of the bitter-orange blossoms for their essential and natural oils. The fruit tree is native to Asia. Agua de azahar is believed to act as a sedative of the nervous system and as an antispasmodic, which naturally relaxes muscles spasms and heart palpitations. It is typically consumed as water or tea.

[0019] Passion flower (*passiflora incarnata*) is an herbal supplement used historically in treating anxiety, insomnia, seizures, and hysteria. Passionflower is a climbing vine that is native to the southeastern United States and Central and South America.

[0020] In some embodiments, the nutritional supplement disclosed herein includes a phytonutrient blend comprising two or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower. For example, in some embodiments, the phytonutrient blend includes valerian root and linden, or valerian root and agua de azahar, or valerian root and passion flower, or linden and agua de azhar, or linden and passion flower, or agua de azahar and passion flower.

[0021] In some embodiments, the phytonutrient blend includes three or more phytonutrient compounds selected from valerian root, linden, agua de azahar, and passion flower. For example, in some embodiments, the phytonutrient blend includes valerian root, linden, and agua de azahar, or valerian root, linden, and passion flower, or valerian root, agua de azahar, and passion flower, or linden, agua de azahar, and passion flower.

[0022] In some embodiments, the phytonutrient blend includes valerian root, linden, agua de azahar, and passion flower.

[0023] In some embodiments, the phytonutrient blend includes valerian root containing 0.5 to 2.5% valeric acids. In some embodiments, the phytonutrient blend includes 25-60% valerian root by weight. In some embodiments, the phytonutrient blend includes 25-50% valerian root by weight. In some embodiments, the phytonutrient blend includes 25-40% valerian root by weight. In some embodiments, the phytonutrient blend includes 25-30% valerian root by weight. In some embodiments, the phytonutrient blend includes 30-60% valerian root by weight. In some embodiments, the phytonutrient blend includes 40-60% valerian root by weight. In some embodiments, the phytonutrient blend includes 50-60% valerian root by weight. In some embodiments, the phytonutrient blend includes 30-50% valerian root by weight. In some embodiments, the phytonutrient blend includes 25-45% valerian root by weight. In some embodiments, the phytonutrient blend includes 30-40% valerian root by weight.

[0024] In some embodiments, the phytonutrient blend includes 5-40% linden by weight. In some embodiments, the phytonutrient blend includes 5-30% linden by weight. In some embodiments, the phytonutrient blend includes 5-20% linden by weight. In some embodiments, the phytonutrient blend includes 5-10% linden by weight. In some embodiments, the phytonutrient blend includes 10-40% linden by weight. In some embodiments, the phytonutrient blend includes 20-40% linden by weight. In some embodiments, the phytonutrient blend includes 30-40% linden by weight. In some embodiments, the phytonutrient blend includes 5-25% linden by weight. In some embodiments, the phytonutrient blend includes 10-25% linden by weight. In some embodiments, the phytonutrient blend includes 15-25% linden by weight.

[0025] In some embodiments, the phytonutrient blend includes 5-40% passion flower by weight. In some embodiments, the phytonutrient blend includes 5-30% passion flower by weight. In some embodiments, the phytonutrient blend includes 5-20% passion flower by

weight. In some embodiments, the phytonutrient blend includes 5-10% passion flower by weight. In some embodiments, the phytonutrient blend includes 10-40% passion flower by weight. In some embodiments, the phytonutrient blend includes 20-40% passion flower by weight. In some embodiments, the phytonutrient blend includes 30-40% passion flower by weight. In some embodiments, the phytonutrient blend includes 5-25% passion flower by weight. In some embodiments, the phytonutrient blend includes 10-25% passion flower by weight. In some embodiments, the phytonutrient blend includes 15-25% passion flower by weight.

[0026] In some embodiments, the phytonutrient blend includes 5-40% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 5-30% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 5-20% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 5-10% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 10-40% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 20-40% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 30-40% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 5-25% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 10-25% agua de azahar by weight. In some embodiments, the phytonutrient blend includes 15-25% agua de azahar by weight.

[0027] Any discussion of numerical values or ranges such as weight percentages and pH values can be understood as referring to the exact values and also reasonable approximations of those values/ranges as would be understood to a person of ordinary skill in the art.

[0028] The nutritional supplement described herein delivers all the age-old traditional benefits of valerian root, linden, agua de azahar, and/or passion flower essence or tincture delivered in a pleasant tasting gummy, gelatin, or other product, that may also be infused with super foods and vitamins. Embodiments of the present disclosure described herein effectively mask the unpleasant flavor of certain phytonutrient compounds, such as valerian root, making the gummy much more appealing to consumers and remove all alcohol found in traditional flower essences, making the nutritional supplement more accessible to consumers desiring the benefit of flower essences without the downsides of alcohol.

[0029] There are many reasons why consumers may not want to use herbs with a high alcohol content, such as disliking the taste or having an alcohol sensitivity. Alcohol can also

stress a weakened or under-functioning liver in sensitive individuals. Further, alcohol is not appropriate for children and young adults.

[0030] As described more fully below, in some embodiments, the one or more phytonutrient compounds and/or botanical extracts are first provided in the form of a concentrate that is used to manufacture the nutritional supplement in a gummy form. In some embodiments, the one or more phytonutrient compounds and/or botanical extracts are provided in the form of a liquid concentrate that is then provided in a gummy form. In some embodiments, any alcohol used to prepare the concentrate is evaporated off during the process of providing the concentrate in a gummy form.

[0031] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend disclosed herein at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement includes the botanical blend at about 5% to about 15% by weight, pectin, tapioca and water.

[0032] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional

supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and/or passion flower, alone or in combination, at about 5% to about 15% by weight, pectin, tapioca and water.

[0033] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein

includes a botanical blend of valerian root and linden at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and linden at about 5% to about 15% by weight, pectin, tapioca and water.

[0034] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 10% to about

20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, and agua de azahar at about 5% to about 15% by weight, pectin, tapioca and water.

[0035] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root and passion flower at about 5% to about 15% by weight, pectin, tapioca and water.

[0036] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 40% by weight,

pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and agua de azahar at about 5% to about 15% by weight, pectin, tapioca and water.

[0037] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 10% to about 40% by weight,

pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden and passion flower at about 5% to about 15% by weight, pectin, tapioca and water.

[0038] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of agua de azahar and passion flower at about 5% to about 15% by weight, pectin, tapioca and water.

[0039] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden and agua de azahar at about 5% to about 15% by weight, pectin, tapioca and water.

[0040] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden,

and passion flower at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, and passion flower at about 5% to about 15% by weight, pectin, tapioca and water.

[0041] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional

supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 10% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of linden, agua de azahar, and passion flower at about 5% to about 15% by weight, pectin, tapioca and water.

[0042] In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 50% by weight, pectin, an oligosaccharide and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 20% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 10% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 10% to about 50% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 10% to about 40% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 10% to about 30% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 10% to about 20% by weight, pectin,

tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 25% by weight, pectin, tapioca and water. In some embodiments, the nutritional supplement disclosed herein includes a botanical blend of valerian root, linden, agua de azahar, and passion flower, alone or in combination, at about 5% to about 15% by weight, pectin, tapioca and water.

[0043] The nutritional supplement described herein deliver all the traditional benefits of linden, valerian root, azahar, and/or passion flower, or combinations thereof, packed into a pleasant and delicious tasting gummy, gelatin, or other food product. In some embodiments, the nutritional supplement described herein is also infused with super foods and vitamins. Embodiments of the disclosure described herein effectively mask the flavor of linden, valerian root, azahar, and/or passion flower, making the nutritional supplement much more appealing to consumers.

[0044] In some embodiments, the formulations described herein mask the unpleasant taste of linden, valerian root, azahar, and/or passion flower without the use of excessive levels of sugar. For example, the use of an amount of sugar that exceeds the solubility point can cause undesirable crystallization and hardening of the supplement. Moreover, excessive sugar can be undesirable for consumers with a goal of minimizing their daily sugar intake for health purposes.

[0045] In some embodiments, the nutritional supplement disclosed herein include an oligosaccharide. In some embodiments, the oligosaccharide is tapioca. In some embodiments, the oligosaccharide is a syrup. Exemplary syrups include, but are not limited to, glucose syrup, corn syrup, rice syrup, invert syrup, isomaltooligosaccharide (IMO) sugar, tapioca, fructooligosaccharide (FOS) syrup, starch, fiber syrup, inulin, fruit puree, fruit concentrate, high maltose syrup, agave syrup, and any combinations thereof. In some embodiments, the syrup can be a tapioca syrup. In some embodiments, corn syrup, such as a high fructose corn syrup, can be used. Some non-limiting concentrations of syrup in the nutritional supplement in weight percentages can include, but not limited to, about 0.1% to about 80%, or about 5% to about 75%, or about 10% to about 70%, or about 15% to about 65%, or about 20% to about 60%, or about 25% to about 55%, or about 30% to about 50%, or about 35% to about 45%, or about 15% to about 80%, or about 25% to about 60%, or about 30% to about 50%. In some embodiments, the concentration of the syrup can be about 1%, or about 10%, or about 15%, or about 20%, or about 25%, or about 30%, or about 35%, or about 40%, or about 45%, or about

50%, or about 55%, or about 60%, or about 65%, or about 70%, or about 75%, or about 80% by weight.

[0046] In some embodiments, the nutritional supplements disclosed herein include a gelling agent. Exemplary gelling agents can include, but not limited to pectin, gelatin, seaweed extract, agar, carrageenan, gum Arabic, and any combinations thereof. In some embodiments, pectin is used as a gelling agent. In some embodiments, gelatin is used as a gelling agent. Some non-limiting concentrations of gelling agent in the nutritional supplement in weight percentages include, but are not limited to, about 0.1% to about 80%, or about 5% to about 75%, or about 10% to about 70%, or about 15% to about 65%, or about 20% to about 60%, or about 25% to about 55%, or about 30% to about 50%, or about 35% to about 45%, or about 15% to about 80%, or about 25% to about 60%, or about 30% to about 50%. In some embodiments, the concentration of the gelling agent is about 1%, or about 10%, or about 15%, or about 20%, or about 25%, or about 30%, or about 35%, or about 40%, or about 45%, or about 50%, or about 55%, or about 60%, or about 65%, or about 70%, or about 75%, or about 80% by weight.

[0047] In some embodiments, the nutritional supplements disclosed herein include a sweetener. In some embodiments, the sweetener can be a disaccharide. Exemplary sweeteners can include, but not limited to, non-organic cane sugar, organic cane sugar, sugar alcohol, natural sweeteners such as stevia or monk fruit, sugar alternatives such as short length carbohydrate, any of the plethora of artificial sweeteners known to one of ordinary skill in the art, and any combinations thereof. Some non-limiting concentrations of sweeteners in the nutritional supplement in weight percentages include, but are not limited to, about 0.1% to about 80%, or about 5% to about 75%, or about 10% to about 70%, or about 15% to about 65%, or about 20% to about 60%, or about 25% to about 55%, or about 30% to about 50%, or about 35% to about 45%, or about 15% to about 80%, or about 25% to about 60%, or about 30% to about 50%. In some embodiments, the concentration of sweeteners is about 1%, or about 10%, or about 15%, or about 20%, or about 25%, or about 30%, or about 35%, or about 40%, or about 45%, or about 50%, or about 55%, or about 60%, or about 65%, or about 70%, or about 75%, or about 80% by weight.

[0048] In some embodiments, the nutritional supplements disclosed herein includes water. Some non-limiting concentrations of water in the nutritional supplement in weight percentages include, but are not limited to, about 0.1% to about 90%, or about 5% to about 85%, or about 10% to about 80%, or about 15% to about 75%, or about 20% to about 70%, or about 25% to

about 65%, or about 30% to about 60%, or about 35% to about 55%, or about 40% to about 50%, or about 10% to about 30%, or about 15% to about 25%, or about 20% to about 30%, or about 25% to about 30%. In some embodiments, the concentration of the water is about 1%, or about 10%, or about 15%, or about 20%, or about 25%, or about 30%, or about 35%, or about 40%, or about 45%, or about 50%, or about 55%, or about 60%, or about 65%, or about 70%, or about 75%, or about 80% by weight

[0049] In some embodiments, the nutritional supplements disclosed herein include an acidifying agent. Exemplary acidifying agents include, but are not limited to lactic acid, formic acid, citric acid, malic acid, fumaric acid, tartaric acid, glucono-delta lactone, salts of gluconic acid, phosphoric acid, succinic acid, adipic acid, ascorbic acid, acetic acid, and any combinations thereof. Some non-limiting concentrations of the acidifying agents in the nutritional supplement in weight percentages include, but are not limited to, from a trace amount to about 20%, or about 0.1% to about 15%, or about 0.2% to about 10%, or about 0.3% to about 5%, or about 0.5% to about 4%, or about 0.7% to about 3%, or about 1% to about 2.5%. In some embodiments, the concentration of the acidifying agent is a trace amount. In some embodiments, the concentration of the acidifying agent is about 0.1%, or about 0.2%, or about 0.3%, or about 0.4%, or about 0.5%, or about 0.6%, or about 0.7%, or about 0.8%, or about 0.9%, or about 1%, or about 2%, or about 3%, or about 4%, or about 5%, or about 6%, or about 7%, or about 8%, or about 9%, or about 10%, or about 11%, or about 12%, or about 13%, or about 14%, or about 15%, or about 16%, or about 17%, or about 18%, or about 19%, or about 20% by weight.

[0050] In some embodiments, the nutritional supplement disclosed herein include a buffer agent. Exemplary acidifying agents include, but are not limited to sodium citrate, magnesium citrate, trisodium citrate, bisodium citrate, any protein or amino acids, and any combinations thereof. Some non-limiting concentrations of the buffer agent in the nutritional supplement in weight percentages include, but are not limited to, from trace amount to about 10%, or about 0.1% to about 7.5%, or about 0.2% to about 5%, or about 0.3% to about 2.5%, or about 0.5% to about 1%. In some embodiments, the concentration of the buffer agent is a trace amount. In some embodiments, the concentration of the buffer agent is about 0.1%, or about 0.2%, or about 0.3%, or about 0.4%, or about 0.5%, or about 0.6%, or about 0.7%, or about 0.8%, or about 0.9%, or about 1%, or about 2%, or about 3%, or about 4%, or about 5%, or about 6%, or about 7%, or about 8%, or about 9%, or about 10% by weight.

[0051] In some embodiments, the nutritional supplements disclosed herein include a flavorant. In some embodiments, the flavorant is an oil. Exemplary oils include, but are not limited to, spearmint oil, peppermint oil, cinnamon oil, oil of wintergreen (methylsalicylate), clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, cedar leaf oil, oil of nutmeg, oil of sage, oil of bitter almonds, cassia oil, and any combinations thereof. In some embodiments, the flavorants include artificial, natural or synthetic fruit flavors, such as, but not limited to, citrus or fruit oils and/or essences including apple, apricot, banana, blueberry, cherry, grape, grapefruit, kiwi, lemon, lime, orange, pear, peach, pineapple, plum, raspberry, strawberry, tangerine and watermelon. In some embodiments, the nutritional supplements disclosed herein include mixtures of flavorants. In some embodiments, the concentrations of the flavorants in weight percentages can be from trace amount to about 1%, or about 0.1% to about 0.9%, or about 0.2% to about 0.7%, or about 0.3% to about 0.6%, or about 0.4% to about 0.5%. In some embodiments, the concentration of the flavorant is a trace amount. In some embodiments, the concentration of the flavorant is about 0.1%, or about 0.2%, or about 0.3%, or about 0.4%, or about 0.5%, or about 0.6%, or about 0.7%, or about 0.8%, or about 0.9%, or about 1%.

[0052] Additional flavorants include, but are not limited to menthol, artificial vanilla, cinnamon derivatives, and various fruit flavors, whether employed individually or in admixture. Flavorings can also include, for example, aldehydes and esters including cinnamyl acetate, cinnamaldehyde, citral diethylacetal, dihydrocarvyl acetate, eugenyl formate, p-methylamisol, acetaldehyde (apple); benzaldehyde (cherry, almond), anisic aldehyde (licorice, anise); cinnamic aldehyde (cinnamon); citral, i.e., alpha citral (lemon, lime); ethyl vanillin (vanilla, cream); heliotropine, i.e., piperonal (vanilla, cream); vanillin (vanilla, cream); alpha-amyl cinnamaldehyde (spicy fruity flavors); butyraldehyde (butter, cheese); valeraldehyde (butter, cheese); citronellal; decanal (citrus fruits); CA 02864531 2014-09-19 aldehyde C-8 (citrus fruits); aldehyde C-9 (citrus fruits); aldehyde C-12 (citrus fruits); 2-ethylbutyraldehyde (berry fruits); tolyl aldehyde (cherry, almond); veratraldehyde (vanilla); 2,6-dimethyl-5-heptenal, i.e., melonal (melon); 2,6-dimethyloctanal (green fruit); and 2-dodecenal (citrus, mandarin), mixtures thereof and the like. Additional flavor compounds include ethylacetate, thiophene, ethylpropionate, ethyl butyrate, 2-hexanoate, 2-methylpyrazine, heptaldehyde, 2-octanone, limonene, and eugenol.

[0053] In some embodiments, the nutritional supplements disclosed herein include a colorant. Exemplary colorants include natural or uncertified colors from natural sources or certified colors for the effect of color. In some embodiments, the colorant includes dyes,

certified aluminum lakes or colors derived from a natural source. The colorant can be water-based, oil-based or dry. The colorant can be primary colors, blends of colors or discrete mixtures of colors, such as confetti. In some embodiments, the concentrations of colorant in the nutritional supplement in weight percentages is from trace amount to about 1%, or about 0.1% to about 0.9%, or about 0.2% to about 0.7%, or about 0.3% to about 0.6%, or about 0.4% to about 0.5%. In some embodiments, the concentration of the colorant is a trace amount. In some embodiments, the concentration of the colorant is about 0.1%, or about 0.2%, or about 0.3%, or about 0.4%, or about 0.5%, or about 0.6%, or about 0.7%, or about 0.8%, or about 0.9%, or about 1%.

[0054] In some embodiments, the nutritional supplements disclosed herein include vitamins. Examples of vitamins include, but are not limited to B vitamins, vitamin C, vitamin E, and any combinations thereof.

[0055] In some embodiments, the nutritional supplements include amino acids, which can include, but are not limited to histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, asparagine, aspartic acid, cysteine, glutamic acid, glutamine, glycine, ornithine, proline, selenocysteine, serine, tyrosine, and combinations thereof. In some embodiments, the nutritional supplements include about 0.05% to 10% amino acids by weight.

[0056] In some embodiments, the nutritional supplements optionally include an emulsifier. Some non-limiting examples of emulsifiers can include, but are not limited to sucrose esters, soy lecithin, sunflower lecithin, egg lecithin, lecithins and combinations thereof. In some embodiments, the nutritional supplements include an emulsifier in weight percentages from trace amount to about 1%, about 0.2% to 0.8%, trace amount to about 0.5%, about 0.5% to 1%, about 0.3% to 0.6%, or about 0.1% to 0.5%.

[0057] In some embodiments, the nutritional supplements can be coated with a wax and/or oil. Some non-limiting examples of suitable wax can include, but are not limited to carnauba wax, bees wax, and the like. Some non-limiting examples of suitable oils can include, but are not limited to mineral oil, coconut oil, vegetable oil, and the like. In some embodiments, the nutritional supplements are further coated with a flavorant, such as sugar granules or flavor particles.

[0058] In some embodiments, the nutritional supplements further include various other ingredients, such as, but not limited to, herbal additives, ascorbic acid, cocoa powder to create

chocolate, cocoa butter, palm kernel oil, sunflower lecithin, or soy lecithin. In some embodiments, the nutritional supplements also include cannabidiol (CBD), ginger, tetrahydrocannabinol (THC), pepper, chili, cayenne, turmeric, collagen, buteric acid, salts or esters of beta-hydroxybutyric acid (BHB), or any combinations thereof. In some embodiments, the nutritional supplements include organic carrot, organic apple, organic blackcurrant, organic beet root, organic pomegranate, or any combinations thereof.

[0059] In some embodiments, the nutritional supplements described herein are provided in another form, including, but not limited to, capsules, chewables, worms, caramel steering, hard candy, or chocolate.

[0060] In some embodiments, the pH levels have desired ranges, but these can vary with the gelling agent. For example, in some embodiments, gelatin, pectin, or carrageenan are used, and the pH is kept between about 2 and 6. In some embodiments, agar is used, and the pH is kept between about 3 and 8. In some embodiments, pectin is used and the pH of the finished product is about 2.5 to 4.

[0061] Furthermore, in some embodiments, various ranges for other properties can assist in the masking of the flavor, such as the water activity (the ratio of the partial pressure of water in the atmosphere in equilibrium with the substrate (e.g., a food) to that of the atmosphere in equilibrium with pure water at the same temperature), brix (the sugar content of an aqueous solution), and levels of acetic acid. In some embodiments, these ranges include a water activity between about 0.3 and 0.85, brix value between about 0.65 and 0.99, and acetic acid levels between about 1% and 50%.

[0062] In some embodiments, the nutritional supplement described herein has a density of from about 0.6 g/cm³ to 1.4 g/cm³, about 0.7 g/cm³ to 1.3 g/cm³, about 0.8 g/cm³ to 1.2 g/cm³, about 0.9 g/cm³ to 1.1 g/cm³, about 0.8 g/cm³ to 1.0 g/cm³, about 1.0 g/cm³ to 1.2 g/cm³, about 0.9 g/cm³ to 1.2 g/cm³, about 0.7 g/cm³ to 1.1 g/cm³, about 0.85 g/cm³ to 1.15 g/cm³, about 0.95 g/cm³ to 1.05 g/cm³, or about 1.05 g/cm³ to 1.25 g/cm³.

[0063] The gel structure of the disclosed nutritional supplement product can be further characterized by textural analysis, such as firmness and resilience (also known as spring back). Firmness and resilience can be measured using a TA.TX texture analyzer (Texture Technologies; Hamilton, Mass.) using conventional methods. Firmness and resilience of the gel structure can be measured in grams force using a TA.TX texture analyzer in compression mode. In some embodiments, the nutritional supplement product can include a gel structure

having a firmness measured in grams force of from about 450 g to 1550 g, about 500 g to 1400 g, about 700 g to 1300 g, about 800 g to 1200 g, about 900 g to 1100 g, about 700 g to 1000 g, about 850 g to 1350 g, about 600 g to 900 g, about 550 g to 750 g, or about 925 g to 1275 g.

[0064] In some embodiments, the nutritional supplement product can include a gel structure having a resilience of from about 20% to 60% spring back after being held under about 20% compression strain for about one minute. In some embodiments, the nutritional supplement product can include a gel structure having a resilience of from about 25% to 55% spring back, about 35% to 45% spring back, about 30% to 50% spring back, about 20% to 40% spring back, about 40% to 60% spring back, about 30% to 60% spring back, or about 25% to 45% spring back after being held under about 20% compression strain for about one minute. Over the shelf life of the nutritional supplement product, the spring back may be reduced by about 10% to 80%, by about 20% to 70%, by about 30% to 60%, or by about 40% to 50%.

[0065] In some embodiments, firmness and/or resilience can be measured at one or more time points during the shelf-life of the nutritional supplement product. In some embodiments, the firmness and/or resilience can be measured at about 0 days to 90 days after production of the nutritional supplement product; at about 1 day to 100 days after production of the nutritional supplement product; or at about 7 days to 80 days after production.

[0066] The nutritional supplement product of the present disclosure can be provided in multiple sizes and shapes as desired, including but not limited to, geometric shapes such as a cylinder, sphere, cube, pyramid, and the like; and novelty shapes such as novelty characters, bears, stars, worms, rings fruit, and the like. In some embodiments, the nutritional supplement product can be in the shape of a substantially rounded cylinder, such as a dot form or rounded, truncated cone, or cylinder form. The individual pieces in that embodiment can have a diameter of from about 14 mm to 18 mm, about 12 mm to 20 mm, about 13 mm to 15 mm, or about 15 mm to 18 mm. The individual pieces in that embodiment can have a height of from about 14 mm to 22 mm, about 15 mm to 20 mm, about 16 mm to 18 mm, or about 17 mm to 22 mm. In some embodiments, the weight of an individual piece can be from about 1 gram to 10 grams, about 1 gram to 8 grams, about 1 gram to 6 grams, about 1 gram to 4 grams, about 2 grams to 4 grams, about 2.2 grams to 2.8 grams, about 2.5 grams to 3.5 grams, or about 3 grams to 4 grams. In some embodiments, the weight of an individual piece can be about 4 grams.

[0067] Those skilled in the art will recognize, or be able to ascertain, using no more than routine experimentation, numerous equivalents to the specific composition and procedures described herein. Such equivalents are considered to be within the scope of this disclosure.

Methods of manufacture

[0068] Traditional methods for extracting botanical compounds from botanical materials (flowers, herbs, etc.) often result in low yields and/or compromised purity. Extracting floral essence according to embodiments of the invention disclosed herein results in high extraction efficiency and increased purity of the final product. Further, traditional methods of extracting botanical essence often result in diluted extracts that lack sufficient concentration for effective use in food products. Still further, the integration of these extracts into gummy formulations can be inefficient, leading to loss of flavor and active compounds. The embodiments described herein provide a scalable method that maximizes the essence of botanical materials while ensuring a high-quality gummy product.

[0069] Using botanical essences in gummies provides therapeutic properties, including improving sleep quality, reducing sleep onset time, and/or enhancing overall sleep duration, while also providing aromatherapeutic benefits that promote relaxation, stress relief, or other positive emotional states. In addition, using botanical essences in gummies provides rich, natural flavors that enhance the taste of gummies without relying on synthetic additives, provides a vast array of botanical materials to choose from, allowing for synergistic combinations of active ingredients that result in diverse flavor profiles and health benefits, and enhances a product's natural and wholesome image. Further, using botanical essences in gummies allows for sustainable sourcing, aligning with the growing consumer demand for environmentally-friendly products.

[0070] Using concentrated phytonutrient compounds and/or botanical blends obtained using the extraction methods disclosed herein yields botanical extracts with large quantities of active ingredients found in the botanical materials to be provided in small volumes in order to obtain full efficacy in gummy form. For example, some botanical materials can be light in weight requiring a large volume of material to yield the desired result. By first preparing a concentrate, such as a liquid concentrate, small volumes of concentrate can be used to obtain full efficacy.

[0071] In some embodiments, a method for extracting the essence of botanical materials, concentrating the extracted liquid, and incorporating the liquid concentrate into a gummy is provided. In some embodiments, the method utilizes controlled extraction of volatile compounds and partial evaporation of water content, resulting in a concentrated liquid. In some embodiments, the use of the concentrated liquid enhances the flavor and therapeutic properties of the gummy product.

[0072] In some embodiments, the one or more phytonutrient compounds are provided in the form of one or more botanical extracts. In some embodiments, the one or more botanical extracts are provided as one or more floral essence compounds. In some embodiments, the one or more phytonutrient compounds and/or botanical extracts are provided as a water-soluble liquid.

[0073] In some embodiments, flower essence extracts are prepared by soaking herbs in an extracting agent called a ‘menstruum’ to draw out active ingredients. A common menstruum is alcohol, which is often used to free the constituents of the herb so it can become more bio-available to the body. Specific instructions on how to prepare a botanical extract are described in the well-respected pharmaceutical texts *The United States Pharmacopeia and National Formulary*. These texts describe methods with a specific ratio for each plant; while this ratio varies, it usually calls for 100-200 grams of dried herb equivalent per liter (approx. quart) of solvent. Many botanical extracts contain a very high percentage of alcohol, often 60-90%. Flower essence extracts are further prepared by evaporating the alcohol leaving the flower essence and water. Flower essence extracts contain a high concentration of herbal constituents and supportive phytonutrients.

[0074] In some embodiments, the method includes extraction of botanical essence comprising the steps of selecting botanical materials known for their beneficial properties, optionally, cleaning and processing the botanical materials by chopping or grinding, soaking the materials in a suitable solvent (e.g., ethanol or water to extract essential volatile compounds and active constituents, and filtering the mixture to separate the liquid extract from the solid material.

[0075] In some embodiments, botanical material is first prepared by harvesting and washing to remove impurities. In some embodiments, botanical material is finely chopped to increase surface area for extraction. Next botanical material is soaked in a selected solvent for

12-24 hours to allow for the dissolution of soluble compounds. The resulting solution is then filtered to remove solid plant material while retaining the liquid extract.

[0076] In some embodiments, the botanical material includes valerian root, linden, agua de azahar, and/or passion flower, alone or in combination. In some embodiments, the essence of the botanical material is first extracted using a solvent such as alcohol and/or water.

[0077] In some embodiments, the phytonutrient compounds used herein are prepared from botanical material soaked in alcohol and/or water. In some embodiments, at least 20% alcohol by volume (ABV) or 40 proof alcohol is used. In some embodiments, alcohol that is between 40-60% ABV (80-120 proof) is used. In some embodiments, alcohol that is 80-100% ABV is used. In some embodiments, vodka, brandy, rum, gin, grain alcohol, or overproof alcohol are used. In some embodiments, ethanol is used.

[0078] In some embodiments, spring water is used. In some embodiments, alkaline water is used. In some embodiments, oxygenated water is used, such as oxygen-rich or ionized water. In some embodiments, flowers are submerged in natural spring water or alkaline water.

[0079] The pH needed to extract floral essences of botanical can vary depending on the botanical material and the extraction method used. The pH is selected to preserve the flavor, aroma, and overall quality of the extracted essence. In some embodiments, for water extractions, a pH of around 6 to 7 is used. In some embodiments, oxygenated water is used at a pH of around 8.5-9.5. In some embodiments, oxygenated water is used at a pH of around 6 to 7. This neutral to slightly acidic range helps to protect delicate botanical compounds during extraction. In some embodiments, oxygenated water enhances the extraction process by promoting oxidation reactions release volatile compounds. In some embodiments, a pH in the lower end of the range (around 5 to 6) is used to improve the solubility of some floral compounds.

[0080] In some embodiments, the mixture of botanical material and solvent is treated to extract the energy of flowers, such as, by boiling or electrifying the solvent or placing the extract in the sun. In some embodiments, the extract is then filtered. In some embodiments, the solvent is evaporated off leaving concentrated essence and water.

[0081] In some embodiments, a method for concentrating the liquid extract is provided wherein the method includes subjecting the liquid extract to controlled evaporation to remove a percentage of the water content. In some embodiments, at least 40% of the water content is removed. In some embodiments, at least 50%, or at least 60%, or at least 70%, or at least 75%

of the water content is removed. In some embodiments, controlled evaporation is performed through gentle heating or vacuum evaporation or other similar processes known in the art. In some embodiments, evaporation of excess liquid occurs under heat conditions that preserve the active properties of the botanical essence. In some embodiments, the temperature and pressure are monitored to preserve the integrity of sensitive compounds while achieving the desired concentration.

[0082] In some embodiments, the botanical extract is purified using distillation methods known in the art. For example, in some embodiments herein, valerian root, linden, agua de azahar, and/or passion flower extract is further purified using distillation techniques known in the art, such as, steam distillation, wherein steam is used to release the active constituents from the plant material and allow them to evaporate with the steam. The steam is then condensed to water as it passes through a cooling chamber. This results in a super concentrated phytonutrient essence, water-soluble liquid to be used in the nutritional supplement sleep products described herein.

[0083] In some embodiments, the filtered extract is then introduced into a steam distillation apparatus, allowing steam to pass through the extract, causing volatile compounds to evaporate. Distillate containing concentrated botanical compounds is then collected. In some embodiments, an evaporator is then used to remove solvent from the distillate, resulting in pure floral extract.

[0084] In some embodiments, GC-MS (Gas Chromatography-Mass Spectrometry) analysis is used to confirm the purity and composition of the liquid extract.

[0085] Using a liquid botanical extract concentrate rather than a powder concentrate for manufacturing the therapeutic gummies disclosed herein has distinct benefits. For example, using liquid concentrate allows for easier integration of the concentrate into the gummy formulation. Liquid concentrates can mix more readily into gummy formulations, ensuring even distribution of flavor and active compounds. In addition, liquid concentrates provide enhanced flavor, often providing a more robust and vibrant flavor profile, which can improve the overall taste of the gummies. Additionally, using liquid concentrate according to the claimed invention helps maintain moisture in the gummy mixture, contributing to a softer texture, which enhances mouthfeel. Further, liquid concentrates can be adjusted easily in concentration without the risk of affecting the texture or structure of the gummy as much as powders might. Finally, using liquid concentrate rather than powder to formulate the

therapeutic gummies disclosed herein provides immediate bioavailability as liquids can be absorbed more quickly by the body compared to powders, leading to faster therapeutic effects.

[0086] The challenges of using liquid concentrates to manufacture the therapeutic gummies disclosed herein include that liquid concentrates are more difficult to preserve and maintain shelf life as moisture can lead to spoilage or microbial growth. In addition, variations in liquid concentration can affect batch consistency. Further, the addition of liquid can alter the overall density and weight of the formulation, requiring adjustments in processing and in other ingredients to manufacture the gummies. Finally, caution must be used when exposing the formulation to heat during gummy production to ensure enough liquid is boiled off while avoiding degradation of botanical compounds in liquid concentrates. Understanding these challenges is crucial for development of a gummy product using liquid concentrates.

[0087] In some embodiments, a method of incorporating a liquid concentrate into a gummy is provided including the steps of preparing a gummy formulation using traditional ingredients (e.g., gelatin, sweeteners, citric acid), boiling off excess liquid from the concentrated extract to achieve a viscous consistency suitable for mixing, combining the concentrated botanical essence with the gummy formulation during the cooking phase, ensuring even distribution throughout the mixture, pouring the prepared gummy mixture into molds and allowing the gummy mixture to cool and set. In some embodiments, the addition of water to the mixture is not required. In some embodiments, the amount of water added to the mixture is lower than for a gummy formulated using a powder extract.

[0088] In some embodiments, boil off point for boiling off the excess liquid is selected to ensure a certain percentage of water and/or alcohol in the liquid concentrate is evaporated in order to form the gummy while still ensuring the active does not degrade. In some embodiments, the boil off point is about 200 degrees Fahrenheit to about 240 degrees Fahrenheit, or about 210 degrees Fahrenheit to about 230 degrees Fahrenheit, about 200 degrees Fahrenheit to about 220 degrees Fahrenheit, or about 210 degrees Fahrenheit to about 215 degrees Fahrenheit.

[0089] In some embodiments, the mixture including a liquid extract is heated at a lower temperature to ensure proper texture and flavor. For example, in some embodiments, the mixture is heated at about 150 degrees Fahrenheit to about 200 degrees Fahrenheit, or about 160 degrees Fahrenheit to about 190 degrees Fahrenheit, or about 170 degrees Fahrenheit to about 180 degrees Fahrenheit. In some embodiments, the mixture is heated at an even lower

temperature, for example, at a temperature of about 90 degrees Fahrenheit to about 150 degrees Fahrenheit, or about 100 degrees Fahrenheit to about 140 degrees Fahrenheit, or about 100 degrees Fahrenheit to about 125 degrees Fahrenheit.

[0090] In some embodiments, liquid concentrates that are sensitive to high temperatures are added to the mixture during or after heating. In some embodiments, the higher moisture content of liquid extracts extends the setting time or require conditions to prevent stickiness.

[0091] The Brix range for gummies manufactured according to the methods disclosed herein, vary based on the sweetness of the extract and the overall formulation. A typical Brix Range for standard gummies is approximately 15°Bx to approximately 30°Bx. Standard gummies often use more sugar or corn syrup, leading to a higher Brix level. For example, fruit-flavored gummies might aim for a sweet spot around 20°Bx to 25°Bx.

[0092] Gummies made according to the methods described herein can have delicate flavors, often leading to a lower Brix range from approximately 10°Bx to approximately 20°Bx. A Brix level in this range provides a moderate sweetness, aligned with the natural sugars from the extract and additional sweeteners used in the gummy formulation. Accordingly, in some embodiments, a lower Brix preserves the nuanced tastes without overpowering them with excessive sweetness.

EXAMPLES

Example 1

[0093] Subjects are asked to use a sleep tracking device such as a watch or ring for 10 nights to record their baseline sleep habits, including, detailed data on sleep quality, duration, disruptions, and estimated REM sleep, deep sleep and light sleep stages by measuring heart rate. This information is used to identify baseline trends for each subject.

[0094] After 10 nights of tracking baseline trends, subjects are administered a therapeutic dosage of the nutritional supplements disclosed herein or a placebo each evening at predetermined time intervals prior to their intended bedtime. Subjects are asked to record the time the nutritional supplement is taken, the time they go to bed, and to continue use of the tracking device to record detailed data on sleep quality, duration, and disruptions for 10 nights.

[0095] Sleep tracking data for each of the subjects receiving a placebo is largely consistent with sleep tracking data prior to taking the placebo while sleep tracking data for each of the

subjects receiving a therapeutic dose of the nutritional supplement disclosed herein reveal markedly improved sleep quality with longer periods of uninterrupted sleep and report waking up feeling more rested than usual.

CLAIMS

What is claimed is:

1. A nutritional supplement for improving sleep comprising a therapeutically effective amount of two or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower, wherein the nutritional supplement is free of synthetic sleep aids, and wherein the nutritional supplement is provided in the form of a gummy.
2. The nutritional supplement of claim 1 comprising a therapeutically effective amount of three or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower.
3. The nutritional supplement of claim 2 comprising a therapeutically effective amount of valerian root, linden, agua de azahar, and passion flower.
4. The nutritional supplement of claim 1, wherein the nutritional supplement is free of melatonin.
5. The nutritional supplement of claim 1, wherein the nutritional supplement is free of alcohol.
6. The nutritional supplement of claim 1, wherein the nutritional supplement is free of cannabis.
7. The nutritional supplement of claim 1, further comprising pectin, an oligosaccharide and water.
8. The nutritional supplement of claim 1, wherein the oligosaccharide is tapioca.
9. A method of manufacturing the nutritional supplement of claim 1 comprising:
extracting the essence of botanical material from two or more of valerian root, linden, agua de azahar, and passion flower in a liquid,
concentrating said extracted liquid, and
incorporating the liquid concentrate into a gummy.
10. The method of claim 9, wherein extracting the essence of botanical material from two or more of valerian root, linden, agua de azahar, and passion flower in a liquid comprises soaking the botanical material in a solvent to allow for the dissolution of soluble compounds.
11. The method of claim 10, wherein the solvent comprises alcohol and water.
12. The method of claim 11, wherein the water is oxygenated water.
13. The method of claim 12, wherein the water has a pH of about 8 to about 9.5.

14. The method of claim 9, wherein incorporating the liquid concentrate into a gummy comprises:

preparing a gummy formulation comprising pectin and a liquid concentrate comprising two or more botanical compounds selected from the group consisting of valerian root, linden, agua de azahar, and passion flower;

boiling off excess liquid from the liquid concentrate to achieve a viscous consistency suitable for mixing;

combining the concentrated liquid concentrate with the gummy formulation and mixing to ensure an even distribution throughout the mixture;

pouring the mixture into molds and allowing to cool and set.

15. A method of improving sleep quality or sleep duration comprising administering a therapeutically effective amount of the nutritional supplement of claim 1 prior to bedtime.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/061811

A. CLASSIFICATION OF SUBJECT MATTER					
INV.	A61K36/73	A61K36/752	A61K45/06	A23G3/48	A61K36/185
	A61K36/84	A61P25/20	A61K47/36		
ADD.					
According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED					
Minimum documentation searched (classification system followed by classification symbols)					
A61K					
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched					
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)					
EPO - Internal					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages				Relevant to claim No.
X	Anonymous: "Gomitas Relajantes", , 30 April 2023 (2023-04-30), pages 1-1, XP093258677, www.facebook.com Retrieved from the Internet: URL:https://www.facebook.com/photo/?fbid=7 58158219136407&set=a.100247074927528				1 - 6, 15
Y	the whole document ----- - / - -				1 - 15
☒ Further documents are listed in the continuation of Box C.					
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13 March 2025			24/03/2025		
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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